Philips Consumer Lifestyle B.V.
Drachten
the Netherlands

Review of the technical dossier for CE marking of the BlueTouch 2.0 and BlueTouch 2.1 (Class IIa), in accordance with the requirements of Annex V + VII of the MDD 93/42/EEC

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R1: includes review of corrective actions

DEKRA Certification B.V
Arnhem, The Netherlands

On behalf of DEKRA Business Line Medical:

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TECHNICAL DOSSIER REVIEW REPORT

1 GENERAL ASPECTS

Submitted manufacturer's compliance documents:

- D000003813 SugarPine Device Description, 1.0, 27-Feb-2015
- D000072741 SugarPine Key differences between BLueTouch 1 1 and BlueTouch Gen 2, March 6 2015
- D000072741 SugarPine Key differences between BLueTouch 1 1 and BlueTouch Gen 2, April 21 2015

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

Philips Consumer Lifestyle B.V. has submitted a Technical Dossier for the BlueTouch 2.0 and BlueTouch 2.1.

The device is a patch that radiates blue LED light (453 nm) device and is used for treatment of muscular back pain on the upper and lower back. The device includes two textile straps for positioning the patch, an enclosure with light engine electronics and mains adapter. It can be controlled via a Blue Tooth connected mobile phone device app (only for Bluetouch 2.1). The Blue tooth app is the difference between Bluetouch 2.1 and 2.2.

The device is a line extension of the existing approved Blue Touch device (PR3092). The devices are compared in the table below:

Specification	***Blue Touch Gen 1 (current approved device)***	***Bluetoch Gen 2 (new PR3840)***
Intended use	Treat back pain during normal daily activities by supplying light and heat to the body (by means of optical power and thermal conduction).	Treatment of musculoskele-tal/muscular back pain by supplying light and heat to the body by means of optical power and thermal conduction.
Mode of operation	manual	Manual and by app
accesories	Upper back (redesigned) strap and lower back strap (with extension strap)	Upper and lower back straps (two sizes)
Maximum radiant power	1.4 W	1.44 W
Device temperature sensors	Yes (on LED-assembly, main PCBA and batteries)	Yes (on main PCBA and batteries)

Specification	***Blue Touch Gen 1 (current approved device)***	***Bluetoch Gen 2 (new PR3840)***
Skin temperature sensor	Yes, Device designed to keep skin temperature below 43 degrees C.	No, Skin temperature sensor is not required to prevent overheating.
Proximity sensor		Yes Based on temperature.
LED assembly	LEDs mounted on 3 rigid PCBs covered by dome-shaped polycarbonate foil	LED-on-textile, LEDs covered by dome-shaped polycarbonate foil
Material of surface touching the skin	Polyurethane foil (ISO10993 compliant)	Polyurethane foil (ISO10993 compliant)

DEKRA Certification B.V. is identified as notified body in the technical dossier.

The BlueTouch 2.0 and BlueTouch 2.1 are classified as class IIa devices according to rule 9 of Annex IX of the MDD 93/42/EEC. The following rationale is used for this classification: All active therapeutic devices intended to administer or exchange energy in a non-hazardous way are in Class IIa.
This classification can be accepted by the DEKRA reviewer.

The conformity assessment route followed is Annex V + VII.

The following critical subcontractors are used for the design and/or manufacture of the device:

- Benchmark Electronics Romania
  Industrial Park Ghimbav
  Street 103C Km 2+115 Hala 3
  507075 Brasov
  Romania

Benchmark is used for production of the OEM module

- Benchmark Electronics B.V.
  Lelyweg 10
  7602 EA
  Almelo Netherlands

Benchmark is used for the design of the light engine and electronics

- Sogeti Nederland B.V.
  Lange Dreef 17
  4131 NJ Vianen
  The Netherlands

Sogeti is used for design and development of the mobile phone device app.
More information can be found in the chapter regarding manufacturing information.

Certification structure:
Philips Consumer Lifestyle has an existing CE certificate (2147098CE01) with the following scope: Patch with blue LED light for the treatment of muscular back pain. The addendum of the certificate mentions the following devices:

- Blue Touch Pain Relief Patch
- Upper back strap PR3721
- Lower back strap PR3723 (including Extension strap PR3723).

The certificate is based on the conformity assessment procedure in accordance with Annex V in combination with Annex VII of the MDD 93/42/EEC for class IIa devices. The certificate is valid until 6 February 2015.

Upon approval of the BlueTouch pain relief patch the addendum of the CE-certificate shall be updated in the following way (changes in bold):

- Blue Touch Pain Relief Patch **(Blue LED light)**
- **Blue Touch 2.0 PR3730 (Blue LED light)**
- **Blue Touch 2.1 PR3740 (Blue LED light)**
- Upper back strap PR3721
- Lower back strap PR3723 (including Extension strap PR3723)

See TDR19/Ac01.

Review focus:
Based on the similarities with the existing approved Bluetouch devices the review will focus on risk management, performance, safety, EMC, usability, software.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q01 The current CE Certificate mentions the Upper back strap PR3721 Lower back strap PR3723 (including Extension strap PR3723). Document D000072741 SugarPine Key differences (March 6, 2015) between BLueTouch 1 1 and BlueTouch Gen 2 mentions that the straps

were changed for Gen 2 (and where PR3721 and PR3723) are mentioned as the new straps.
Please explain:

1. if the reference to streps has remained the same from generation 1.0 to 2.0. And if so, how this is treated for generation 1.0 devices.
2. If the reference to the generation 2.0 streps was wrong.

Response Philips:
The straps are interchangeable as explained in section 6 of Key differences between BlueTouch 1.1 and BlueTouch Gen 2 document ID D000072741 dated 2015-04-21 (file location in STED: 1.1.1 Project Identification). New straps (part numbers: PR3721 and PR3723) were approved by DEKRA by NOC number: 2179617-RL01-R0. Therefore the Addendum to Certificate 2147098CE01 was changed to reflect the new one size straps (Upper back strap PR3721, Lower back strap PR3723, including extension strap PR3723).

Comments DEKRA Certification:
The answer is clear and accepted. This question is closed.

2 DEVICE DESCRIPTION

Submitted manufacturer's compliance documents:

- D000003813 SugarPine Device Description, 1.0, 27-Feb-2015

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

The BlueTouch Pain Relief Patch is a soft-shelled pad with 40 light-emitting diodes (LEDs), giving blue light at a nominal wavelength of 453 nm for the treatment of muscular back pain. The BlueTouch patch is intended to be used on the upper and lower back and can be positioned and adjusted on the treatment area by means of two textile straps, particularly designed for both treatment areas. The patch is controlled either via an app on a mobile device or manually.

Intended use

The system is a wearable medical device that intends to treat musculoskeletal/muscular back pain by supplying light and heat to the body by means of optical power and thermal conduction. Special blue LED light relaxes and helps heal damaged muscles through improved blood circulation. The system is intended to be used on the upper or lower back and can be positioned on the treatment area by means of a strap. The device is powered by built-in, non-exchangeable rechargeable batteries. The system can be used during normal daily activities. The system is intended to be only used and operated by persons older than 18 years.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met.

3 RISK MANAGEMENT

Submitted manufacturer's compliance documents:

- D000003815 SugarPine RiskManagementPlan
- D000003816 SugarPine Safety Risk Management Report
- D000001402 SugarPine User FMEA
- D000001417 SugarPine Design FMEA
- D000001439 SugarPine Safety Risk Assessment
- D000003359 SugarPine App User FMEA
- D000003817 SugarPine Safety Risk Management Evaluation Report
- D000001435 SugarPine Verification Report

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN ISO 14971:2012, Medical devices - Application of risk management to medical devices

Review description and results:

The manufacturer has submitted risk management documentation based on the international harmonized standard EN ISO 14971:2012.

The Risk Management documentation describes the product, including accessories.

A Risk Management plan for the lifetime of the product is provided. It could be verified that the plan describes:

- Scope; description of the device and life-cycle phases
- Responsibilities and authorities
- Requirements for review
- Criteria for acceptable levels
- Verification activities
- Activities, collection and review of production and post-production information

The individuals (expertise) that participated in the set up of the Risk Analysis are identified:

Name	Function	Responsibilities
Golo von Basum	Integral Project Lead	Project Management
Peter Bentvelsen	Development Lead	Design Risks
Jeroen de Schrijver	Safety, Compliance and Regulatory Manager	Safety Risks

Maarten Brugmans	Product Researcher	Usability engineering
Michal Wojczulis	Quality Assurance Manager	Coordination
Jan Willem des Bouvrie	Supplier Development Engineer	Supplier Risks
Elke Naujokat	Senior Clinical Researcher	Claim documentation and substantiation

The competences and expertise of the risk management team can not be accepted by the reviewer to cover the applicable subjects for the device under review, see TDR19/Q02.

The main hazards of the product for the patient and/or user are:

- Thermal energy (different scenarios)
- Optical energy
- Water spillage on the device

Since the device has only limited changes to the generation 1.0 of the device the review focused on the differences, this has lead to question nr TDR19/Q03.

The manufacturer has provided a statement that device intended use constitutes acceptable risks when weighted against the benefits to the patient and is compatible with a high level of protection of health and safety (MDD, Annex I, ER 1).

The submitted risk management documentation can not be accepted by the reviewer. Implementation of risk control measures will also be reviewed in the remainder of this report.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q02 The Risk Management Plan does not clarify whether the Risk Management Team has enough expertise on software available. Please elaborate on this.

Response Philips:
Mobile App was developed by Sogeti. The Sogeti Risk Management Plan is located in STED file in section 5.1.3 Software Validation – App/ Software Plans App. The Soegti QA Manager is trained in IEC60601-1 3rd ed., has 6 years of experience in test and integration of medical device software and has followed project internal training in IEC14971 and IEC62304 at customers of Sogeti. Training records reside with the aforementioned

projects and customers. All other project members have the experience and knowledge to perform the activities related to their roles and are guided in IEC62304 and IEC14971 by the QA manager.

Comments DEKRA:
Risk management Plan RMP-PPRAP v1.2 was reviewed. It was observed that the competneces of the risk management team at Sogeti did sufficiently cover expertise on software. This question is closed.

TDR19/Q03 The safety Risk Assessment states that the thermal energy may not be too high causing the skin and the device to become too hot. Please elaborate on:

1. Generation 1 was allowed a max temperature of 43 ^{0}C. The user manual gives maximum values up to 47^{0}C. Please explain why this higher max temperature is deemed acceptable.
2. Please elaborate on how it is validated what the maximum skin temperature is.
3. Design verification report mentions under VP762 that the treatment shall stop if the temperature measurement function is not operational. This seems to indicate that the temperature is monitored; which is in contradiction with the description of the changes (no temperature sensor required.
4. Design verification report mentions under VP886 that requirement AD333 is not tested because it was tested under previous prototype. Please refer to these previous tests and state whether this requirement is met.

Response Philips:

1. The BlueTouch Gen 2 is a device that treats back pain by supplying heat and light to the body (see intended use document D000003813). Because the device is intended to supply heat to the patient, clause IEC60601-1: 11.1.2.2 (ID: RME330) is not applicable and therefore a max temperature of 43 degrees when the device is used for more than 10 minutes is not required. For BlueTouch Gen 2 clause IEC60601-1: 11.1.2.1 (ID: RME329) is applicable (as stated in the risk management file “D000003817 SugarPine Safety Risk Management Evaluation Report”). As requested in the latter clause, clinical risks associated with hazards were identified and they are disclosed in the instructions for use, as well as the maximum

temperatures and clinical effects. For BlueTouch Gen 2 the maximum temperatures are up to 470C.

Comments DEKRA:
The provide answer is accepted. This part of the question is closed.

2. This is explained in D000003548 SugarPine Architectural Design in Section 6 - thermal design. A two-way approach was used to validate the maximum skin temperature.
   Approach 1: Section 6.1 - 6.5 uses a statistical approach based on a trial with PR3092 devices (AWB trial; AWB = Anwendungsbeobachtung, observational trial) that was conducted in the first half of 2014 in Germany. The trial was done with 630 patients using the devices for in total more than 10,000 treatments. Treatments were logged by the devices; the log data sets also contained temperature information. From the statistical analyses the 99.9968% percentile value of the maximum skin temperature during a treatment in program 1, 2 and 3 was determined.
   In section 6.6 it is shown that the thermal response of the BlueTouch Gen 2 device is similar to the response of the PR3092 device that was used during the AWB trial and therefore the results of the statistical analyses also apply for the BlueTouch Gen 2.
   Approach 2: In section 6.7 a thermal model for the interaction between the BlueTouch Gen 2 and skin was used to determine the maximum skin temperatures. The results of the statistical approach (= approach 1) and the model driven approach are in good agreement, though the thermal model slightly underestimates the maximum skin temperature compared to the results of the statistical approach. Therefore the highest predicted skin temperatures that follow from the statistical approach are taken to disclose in the DFU the maximum skin temperatures reached during a treatment.

Comments DEKRA:
It was observed that the thermal behaviour of the skin temperature during use of the Blue Touch device was evaluated based on a statistical model fitted to the data obtained during the AWB trial.
The model provides a very likely model for the determination of the maximum skin temperature. Further more the PMS plan PR-PMS-01 addresses the monitoring of temperature related user feedback. This question is closed.

3. Test ID VP762 in the design verification report reflects the requirement for the temperature of the light engine (LE140). The temperature of the light engine is monitored in order to prevent the device from getting too hot internally as mentioned in HBSRA20 in the safety risk assessment.

Comments DEKRA:
The provide answer is accepted. This part of the question is closed.

4. Two engineering builds of BlueTouch Gen 2 were made: Proto-B and Proto-C as described on page 3/336 in “D000001435 SugarPine Verification Report”. Run 1 in the verification report was done with Proto-B, run 2 with Proto-C.
   To further elaborate on this question:
   With previous prototype we mean Proto-B (run 1) in “D000001435 SugarPine Verification Report”. In section 12 (Run 1 verification results) on page 63/336 of “D000001435 SugarPine Verification Report” we refer to this test with verdict “Pass”.

Comments DEKRA:
It was observed that a valid rationale was provided in D00001435 for not repeating the test related to AD333 for Proto-C. This part of the question is closed.

4 ESSENTIAL PRINCIPALS AND EVIDENCE OF CONFORMITY

Submitted manufacturer's compliance documents:

- D000003810 SugarPine MDD Essential Requirements Checklist, 08-05-2015
- R3731-3733-3741-3743-3721-3723 Draft EU Declaration of Conformity

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- List of harmonized standards published in the Official Journal – OJ C 014 of 16/01/2015

Review description and results:

List of international (or other) standards

The manufacturer has provided a list of all applicable standards (European or other standards used by manufacturer), including year of reference, which are actually used by the manufacturer. The DEKRA reviewer can not accept the list to cover the applicable product standards for BlueTouch 2.0 and BlueTouch 2.1, see TDR19/Q04.

Essential Requirements

The manufacturer has provided a checklist, to show how compliance with the Essential Requirements (following Annex I of the MDD) is addressed.
In the checklist reference is made per Essential Requirement to:

- The Essential Requirements
- Whether the requirement is applicable to the device and if not, a specification why not
- Actual standards used by the manufacturer including version which are used to demonstrate compliance to the Essential Requirements
- The precise identity of the controlled document(s) that offers evidence of conformity

The Essential Requirements checklist provided for BlueTouch 2.0 and BlueTouch 2.1 did fulfill the above stated criteria. The DEKRA reviewer concludes that the Essential Requirements checklist is deemed sufficient, with the exception of TDR19/Q04.

Declaration of Conformity (draft)

The manufacturer has provided a Declaration of conformity for the submitted products and accessories. The contents of the Declaration of Conformity were reviewed and can be accepted. The submitted Declaration of Conformity contains the name and address of the

manufacturer, identification of the notified body, reference to the Medical Device Directive 93/42/EEC, conformity assessment route, classification of the device and time related information, see TDR19/R01.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Minor non-conformities:

TDR19/R01 The draft DoC does not

1. refer to DEKRA Certification B.V as the notified Body (DEKRA is mentioned)
2. Refers as a remark to a TENS device that is not applicable for this submission.
3. Refers to the RoHS Directive and R&TTE Directive, From the DoC it should be clear that these directives are not reviewed by DEKRA Certification B.V.

Response Philips:
Draft Declaration of Conformity has been updated accordingly.

Comments DEKRA:
The provided updated DoC was reviewed. It was observed that the items mentioned above were sufficiently addressed. This minor non-conformity is closed.

Question(s):

TDR19/Q04 Please explain why the harmonized standard EN 62366 on usability is not mentioned as applied standard in the Essential Requirements Checklist.

Response Philips:
Standard was not included in the Essential Requirements Checklist by human error while the product did was developed according the standard (ref. D000003808_SugarPine_Usability Engineering File). The document has been updated including standard EN 62366.

Comments DEKRA:
The submitted ER checklist was reviewed. It was observed that the document contained proper references to EN62366. This question is closed.

Summary of Design Verification/Validation

Submitted manufacturer's compliance documents:

- 2175960.50A (DEKRA test report IEC 60601-1:2005)
- 2175960.50B (DEKRA test report IEC 60601-1-6:2010)
- 2175960.50C (DEKRA test report IEC 62366:2007)
- 2175960.50D (DEKRA test report IEC 60601-11:2010)
- 2175960.50E (DEKRA test report IEC 60601-2-57:2011)
- EMC-15-TRP-4641-401, 13-02-2015
- EMC-15-TRP-4641-501, 13-02-2015
- EMC-15-TRP-4641-502, 13-02-2015
- D000001429 SugarPine Design verification strategy, 21-4-2015
- D000001430 SugarPine Test Design, 21-4-2015
- D000001435 SugarPine Verification Report, 21-4-2015
- D000001401 SugarPine Validation report, 26-2-2015
- D000003808 SugarPine Usability Engineering File, 21-4-2015

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 60601-1:2006 / AC:2010, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2007 / AC:2010, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-6:2010, Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-2-57, Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- EN 60601-1-11:2010, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 62366:2008, Medical devices - Application of usability engineering to medical devices

Review description and results:
The product verification and performance review is based on the product specifications and requirements of Philips Consumer Lifestyle B.V. Philips Consumer Lifestyle B.V. has provided the system requirements for the BlueTouch 2.0 and BlueTouch 2.1.

Philips has provided a verification report for al requirements. Part of these requirements were already treated as part of the risk management, due to the focus of the reviewer on changes to the devices. It was verified whether all tests were met.

Safety of Medical electrical devices
The BlueTouch 2.0 and BlueTouch 2.1 of Philips Consumer Lifestyle B.V. has been tested against various safety standards applicable for medical electrical devices. The focus of the safety tests are the subjects covered in the IEC 60601 – series, except software, EMC and Usability aspects which are described below.
These safety tests were out-sourced to accredited laboratories for these standards. The DEKRA Certification laboratories were used for testing against the standard(s):

- IEC 60601-1:2005
- IEC 60601-11:2010
- IEC 60601-2-57:2011

The DEKRA Certification laboratories conclude that the equipment under test fulfills all relevant requirements of the standard(s).

All the reports were briefly reviewed by DEKRA. The conclusion is that the applicable requirements were met. Some requirements were deemed not applicable (based on risk management) or failed (with reasoning why this is acceptable). This is accepted by the reviewer, accept for some requirements, see TDR19/Q05 and Q06.

Electromagnetic compatibility
The BlueTouch 2.0 and BlueTouch 2.1 of Philips Consumer Lifestyle B.V. has been tested against the EMC requirements which are described in the following standard(s):

- EN 60601-1-2:2007 / AC:2010
- ETSI ENI 301 489-17: 2012
- IEC 60601:2005

These EMC tests were out-sourced to accredited laboratories for these standards. The Philips Innovation Services EMC center laboratories were used for testing against these standards.

The focus of the EMC review is on the results of emission and immunity testing, including specific labeling aspects regarding EMC. The Philips Innovation Services EMC center laboratories conclude that the equipment under test fulfills all relevant requirements of the standard(s).

The device is classified as not life supporting equipment for immunity levels according to EN 60601-1-2 and Class B and Group 1 for emission levels according to CISPR11.
These classifications can be accepted by the reviewer.

All the reports were briefly reviewed by DEKRA. The conclusion is that the applicable requirements were met, accept for TDR19/Q07.

Usability
From the usability engineering file it could be verified that the manufacturer has determined the following aspects:

- Frequently used functions
- Identification of hazards and hazardous situations related to usability
- Primary operating functions
- Usability specification
- Usability validation plan
- User interface design and implementation
- Usability verification
- Usability validation

Philps has provided a usability engineering file and a validation report.
The usability engineering file claims conformance to EN62366 and describes the changes with regard to version 1, see TDR19/Q08. The validation report has a separate section for the app and also treats the straps sufficiently.

From the submitted information it can be concluded that the usability aspects for BlueTouch 2.0 and BlueTouch 2.1 are sufficiently taken into account. Reasoning why requirement fails were given and accepted. However the amount of fails on the strap is rather high, see TDR19/Q09.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q05 The design verification report does not sufficiently describe why:

1. VP19 and VP20 were accepted without assessing impact on safety and performance (corrective actions are defined but do not seem to be implemented)
2. VP 27 is not clear on the specification and why the fail result was accepted (what will be the impact).
3. VP33, recharging within 55 hours failed. Corrective actions were defined. How do these corrective actions impact electrical safety and EMC.
4. VP1199 radiant power failed. Why is this accepted where this might be critical to the safety and performance of the device.
5. VP1202 is not tested (The wireless connection shall be disabled when the device is connected to adapter or PC via a USB cable.) What is the risk of this test not being compliant.
6. VP767 temperature measurement accuracy is less accurate than required. Please elaborate why this is accepted because this might impact patient safety.
7. VP880 was not executed while the printed box was not available. Please explain if this test will be performed at a later stage or otherwise explain why this is not needed.
8. VP1040 is not tested (the app shall support following devices), please explain why this is not done.
9. VP1049-VP1112 are not tested but seem to be more applicable for a TENS device, please explain.
10. VP1113-VP1176 do not seem to have been tested. Please explain

Response Philips:

These DEKRA comments arise from confusion after reading the Design verification report. The report contains the results of run 1 and 2 as is explained in Section 2 of the report:

- Verification run 1 is the verification of the first engineering build of the BlueTouch Gen 2 (“Proto B”)
- Verification run 2 is the verification of the second engineering build of the BlueTouch Gen 2 (“Proto C”)

After verification run 1, failed items were registered as PR’s (Problem Reports) and corrective actions were taken: design changes, manufacturing process changes or requirement changes (in accordance with intended use,

user needs and marketing insights). These changes were implemented in the second engineering build ("Proto-C"). Hence, requirements that failed / weren't tested in Run 1 but passed in Run 2. result in a pass for the final verdict of BlueTouch Gen 2.
Section 5 of the Design verification report contains a summary after verification runs 1 and 2. Of these tests, 460 passed, 2 are ongoing and 2 are accepted fails. In table 1 in Section 5 the verdict remark and decision of the ongoing test and accepted fails are given. In summary: the 2 ongoing tests and 2 accepted fails do not affect safety and effectiveness.

For the sake of completeness we address the 10 review comments of DEKRA below separately:

1. *"VP19 and VP20 were accepted without assessing impact on safety and performance (corrective actions are defined but do not seem to be implemented)"*
   ➔ VP19 and VP20 were failed in Run 1, but passed in Run 2. Hence, final two verdicts are pass.
2. "VP 27 is not clear on the specification and why the fail result was accepted (what will be the impact). "
   ➔ VP27 was failed in both Run 1 and Run 2. Hence, final verdict is fail. Fail result was accepted because, as described in table 6 in section 10: "Average button press force is 11.6N with standard deviation 0.9N; 4 out of 31 samples have button press force >13N (up to 13.6N). 3σ upper boundary is 14.3N. Customer reviews organized by Marketing did not reveal negative feedback on the press force of Run 2 Proto-C devices. Safety and effectiveness are not affected. Fail is accepted. See CR1725."
3. "VP33, recharging within 55 hours failed. Corrective actions were defined. How do these corrective actions impact electrical safety and EMC. "
   ➔ VP33 was failed in Run 1, but passed in Run 2. Hence, final verdict is pass.
4. *"VP1199 radiant power failed. Why is this accepted where this might be critical to the safety and performance of the device. "*
   ➔ VP1199 was failed in Run 1, but passed in Run 2. Hence, final verdict is pass.
5. *"VP1202 is not tested (The wireless connection shall be disabled when the device is connected to adapter or PC via a USB cable.) What is the risk of this test not being compliant. "*
   ➔ VP1202 was untested in Run 1, but passed in Run 2. Hence,

final verdict is pass.

6. *"VP767 temperature measurement accuracy is less accurate than required. Please elaborate why this is accepted because this might impact patient safety. "*
   ➔ VP767 was untested in Run 1, but passed in Run 2. Hence, final verdict is pass.
7. *"VP880 was not executed while the printed box was not available. Please explain if this test will be performed at a later stage or otherwise explain why this is not needed. "*
   ➔ VP880 was not tested in Run 1, and for Run 2 the test is still ongoing. As also mentioned in table 6 in Section 10: *The test covers the discoloration of the packaging when exposed to sunlight. The test is not yet finished. The impact of the light fastness test is cosmetical, safety and effectiveness are not affected.* We conclude that the test has to finished and for now we accepted VP880 as pass because of comparable results of similar products (See table 1, Section 5 Results after verification runs 1 and 2 where this is mentioned)
   The test will be executed for product launch. As also described in section 8 –Final conclusions: "Philips ISE has a Quality Management System in place that guarantees that all compliance evidence needs to be available before Commercial Release is approved."
8. *"VP1040 is not tested (the app shall support following devices), please explain why this is not done. "*
   ➔ VP1040 was untested in Run 1, but passed in Run 2. Hence, final verdict is pass.
9. *"VP1049-VP1112 are not tested but seem to be more applicable for a TENS device, please explain. "*
   ➔ VP1049-VP1112 are not tested in Run 1, but passed in Run 2. Hence, final verdict is pass.
10. *"VP1113-VP1176 do not seem to have been tested. Please explain"*
    ➔ VP1113-VP1176 are not tested in Run 1, but passed in Run 2. Hence, final verdict is pass.

Comments DEKRA:

The provide answer is accepted. This part of the question is closed.

TDR19/Q06 The design verification report does describe accepted fails, however not all fails or not tested parameters are described in this section. Why does Philips accept the verification without approving all failed, not tested and ongoing requirements verifications, especially since some of these requirements might be critical for safety and performance.

Response Philips:
This DEKRA review comment is closely related with TDR19/Q05. TDR19/Q06 arises from confusion after reading the Design verification report. The report contains the results of runs 1 and 2 as is explained in Section 2 of the report:

- Verification run 1 is the verification of the first engineering build of the BlueTouch Gen 2 (“Proto B”)
- Verification run 2 is the verification of the second engineering build of the BlueTouch Gen 2 (“Proto C”)

After verification run 1, failed items were registered as PR’s (Problem Reports) and corrective actions were taken: either design changes, manufacturing process changes or requirement changes (in accordance with intended use, user needs and marketing insights). The changes were implemented in the second engineering build (“Proto-C”). Hence, requirements that were failed/untested in Run 1 but passed in Run 2, result in a pass for the final verdict of BlueTouch Gen 2.

Section 5 of the Design verification report contains a summary after verification runs 1 and 2. Of these tests, 460 passed, 2 are ongoing and 2 are accepted fails. The reasoning for the 2 ongoing and 2 accepted fails are given in table 1 in Section 5. In summary: the 2 ongoing tests and 2 accepted fails do not affect safety and effectiveness.

Comments DEKRA:
The provide answer is accepted. This part of the question is closed.

TDR19/Q08 The validation report has 6 tested parameters on the (new) strap. 4 of these parameters failed. Each fail was individually accepted. Please elaborate on the fact why Philips has accepted the usability of this new strap when 4 of 6 measured parameters failed to the requirements.
In addition, please elaborate on the overall acceptability of the validation report.

Response Philips:
The validation report describes in total 13 requirements on user interaction with the (new) strap, being UR56, UR177, UR53, UR178, UR54, UR98, UR131, UR132, UR133, UR129, UR150, UR100 and UR101 (see D000001401 SugarPine Validation report). These requirements were validated during the Usability Validation test (more information on the Usability Validation process in D000003808_SugarPine_Usability Engineering File).

All of those 13 requirements are evaluated for both the Lower Back Strap (LBS) and for the Upper Back Strap (UBS). For the Lower Back strap all of the 13 requirements are passed. For the Upper Back strap, 4 out of the 13 requirements did not pass. A residual risk/benefit analysis for the UBS was conducted with the following outcome:
The results for UR132 (The user shall be able to wrap the strap around body part), UR133 (The user shall be able to fasten the strap), UR129 (The user shall be able to loosen the strap) and UR56 (The user shall be able to apply the strap in an easy way) are all passed for the UBS (as well as for the LBS), which means the basic workflow of daily interaction with the strap is safeguarded. The 4 requirements that did not pass for the UBS are UR177 (Applying the strap on the body shall be comfortable), UR53 (Wearing the strap with patch shall give a comfortable experience during typical use), UR178 (The strap shall fit the body posture well, when standing and sitting) and UR54 (The patch shall stay in place during typical use). Failing these requirements will not lead to safety related usability problems, only potentially to user annoyance and dissatisfaction. Besides, the results were very close to the target of 80%, being respectively 75%, 75%, 75% and 73%, therefore the occurrence is expected to be low. These considerations have led to the decision to accept the fails.
The Validation report has been updated with a summary of above statement, see D000001401 SugarPine Validation report.

Comments DEKRA:
The provide answer is accepted. This part of the question is closed.

5 SOFTWARE

Submitted manufacturer's compliance documents:

- 0397.4317.5_SRSBlueTouch_SD_v2.0
- 0397.4317.31_SSTSBlueTouch_SD_v3.0
- 0397.4317.53_ERS_SD_v2.0
- 0397.4317.55_EVP_SD_V2.0
- 0397.4317.57_EVR_SD_v2.0
- 0397.4317.61_SSTRBlueTouch_SD_v3.0
- TM-PPRAP v1.8
- TM-PPRAP v1.3
- EVR-PPRAP v 1.5
- FMEA-PPRAP 17-4-2015

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 62304:2006 / AC:2008, Medical device software - Software life-cycle processes

Review description and results:

The software of BlueTouch 2.0 and BlueTouch 2.1 of Philips Consumer Lifestyle B.V. is embedded software.

Focus of the review has been on the app software since the main difference with regard to version 1.0 is in the use of an app. The software verification report of the app describes the requirements, tests performed, remaining bugs and the acceptability, use of SOUP, test equipment, deviations, sprint planning.

A set of SW documents for the device software was provided, see TDR01/Q10 and Q11.

The software version submitted is version 2.0 for the app.

The DEKRA reviewer has reviewed the documentation on the following aspects: risk acceptance criteria, completeness of SW specifications, test plans covering the specifications, verification and validation test are completed and all the acceptance criteria were met. DEKRA cannot accept the results.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q09 The App verification report states that the device has been tested on iOS devices and Android devices. The report does not specifically address:

1. Which Android versions were tested
2. Additionally it is not clear to the reviewer whether Android testing is sufficient (with which Android versions does Philips claim compatibility).
3. Is the risk of having a non-compliant android /iOS version assessed?

Response Philips:
1/2. Ref. SAD-PPRAP_SoftwareArchitecutreDocument.pdf (STED file location: 5. Summary of Design Verification and Validation\5.1 Design Assurance (Bench testing)\5.1.3 Software Validation - App\Software end verification App)

Comments DEKRA:
The Software Architecture Document indicates Android versions 4.4.x & 5.0.x. The testedandroid versions were also 4.4 (on Galaxt Note 10.1) and 5.0 (on Galaxy S4). This part of the question is closed.

3. Yes. FMEA-PPRAP.xlsx #2 (STED file location: 05. Quality Documentation\STED\5. Summary of Design Verification and Validation\5.1 Design Assurance (Bench testing)\5.1.3 Software Validation - App\Software Risk Analysis App)

Comments DEKRA:
It was observed that the risk associated with a wrong version was sufficiently assessed in risk #2 of the submitted document. This part of the question is closed.

TDR19/Q10 Philips claims compliance to EN 62304. Please provide EN 62304 evidence that the requirements of this standard are fulfilled (e.g. by checklist) for both app and device software.

Response Philips:
Ref. D000001438 SugarPine Test Report IEC 62304.pdf

(Location in STED File: 5. Summary of Design Verification and Validation\5.1 Design Assurance (Bench testing)\5.1.3 Software Validation - App\IEC 62304 compliance report App)

Comments DEKRA:
The document D000001438 contains an appropriate EN 62304 checkllist. This question is closed.

TDR19/Q11 The software documentation for the device (folder 5.1.3 SW validation – Device) is unclear for the reviewer. Please provide an overview of which documentation is used for which reason (see Q10). Traceability to system requirements, traceability matrix. software classification and other parts seem to be missing.

Response Philips:
In folder “5.1.3 SW validation – Device” the following documentation (controlled documents by supplier Benchmark) can be found:

0397.4317.5_SRSBlueTouch_SD_v2.0	Software requirements specification
0397.4317.31_SRSBlueTouch_SD_v3.0	Software test specification
0397.4317.53_ERS_SD_v2.0	Electronics requirements specifications
0397.4317.55_EVP_SD_v2.0	Electronics Verification plan
0397.4317.57_EVR_SD_v2.0	Electronics Verification Results
0397.4317.61_SSTRBlueTouch_SD_v3.0	Software test results

The traceability from system requirements (Philips) to device software (Benchmark) is described in document “Benchmark Traceability Matrix” and has been added for reference of the reviewer.

Comments DEKRA:
The submitted documents were reviewed and accepted. This question is closed.

6 BIOCOMPATIBILITY

Submitted manufacturer's compliance documents:

- D000072221 SugarPine Biological Safety Evaluation Report, 21-4-20015

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN ISO 10993-1:2009 / AC:2010, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Review description and results:

For showing biological safety, the European harmonized standard EN - ISO 10993, should preferably be used. Philips has analyzed from this standard that a biological evaluation (Annex A) is to be performed

The BlueTouch 2.0 and BlueTouch 2.1 are categorized according to EN ISO-10993, part 1 as:

- surface device
- skin ;
- contact duration: less than 24 h.

Biocompatibility standard EN ISO 10993-1 requires that the following biocompatibility aspects are addressed:

- Material characterization (the characterization shall at a minimum address the constituent chemicals of the device and possible residual process aids or additives used in its manufacture).

Biocompatibility standard EN ISO 10993-1 requires that the following biocompatibility aspects are addressed (if required in part 1):
Cytotoxicity
Sensitization
Irritation or Intracutaneous reactivity

Philips has assessed which parts of the device can contact the patients: the lower cover foil of the patch and straps, see TDR19/Q12.

The DEKRA reviewer can not accept the assessment of biological safety.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q12 Please provide the certificate number 4659CIT (CITEVE) (Oeko-Tex Standard 100 product class II and the biocompatibility test reports for the lower cover foil (or indicate if the same cover foil is used as for generation 1 cover foils).

Response Philips:
Straps approved by DEKRA via NOC number: 2179617-RL01-R0. Therefore the Addendum to Certificate 2147098CE01 was changed to reflect the new one size straps (Upper back strap PR3721, Lower back strap PR3723, including extension strap PR3723). Oeko-Tex Standard 100 product class II is available dated 24.03.2015.

The bottom part of the device is covered with polyurethane foil Dartex Endurance END409.
-This foil passed irritation test as documented in "Biocompatibility Reports cover note END409" and "ISO10993-10 Irritation Endurance Range 41302715".

Comments DEKRA:
The provided documents were reviewed and accepted. This question is closed.

7 CLINICAL EVALUATION

Submitted manufacturer's compliance documents:

- D000001403 SugarPine Clinical Evaluation Report

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN ISO 14155:2011, Clinical investigation of medical devices for human subjects - Good clinical practice
- EN ISO 14971:2012, Medical devices – Application of risk management to medical devices
- MEDDEV 2.7/1 rev. 3, December 2009, Clinical evaluation: Guide for manufacturers and notified bodies
- MEDDEV 2.7/3 Clinical investigations: SAE reporting under Dir 90/385/EEC and 93/42/EEC
- MEDDEV 2.7/4 Guideline on Clinical Investigations
- MEDDEV 2.12/2 rev. 2, January 2012, Post Market Clinical Follow-up studies

Review description and results:

The manufacturer supplied the documentation as required by the MEDDEV 2.7.1/ rev 3.0. The manufacturer has the same claims as for generation 1.0 devices and also the performance of the device did not change with regard to generation 1.0. It could be found that the clinical evaluation report was updated on February 09, 2015. It was concluded that the conclusions of the clinical evaluation report from 2011 still hold.

The DEKRA reviewer can accept the clinical evaluation.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

8 MANUFACTURING INFORMATION

Submitted manufacturer's compliance documents:

- D000003813 SugarPine Device Description, 1.0, 27-Feb-2015
- Subcontractor certificates as mentioned below
- QF4890 Benchmark Process Flow ref 009
- CP0244-Philips Sugar Pine rev.001

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

The manufacturer has identified the following critical (sub-) contractors that have a role in the manufacture of the device:

Component	***Description activities***	***Subcontractor***	***Certification***
Blue touch device	Production	Benchmark Electronics Romania S.R.L.	ISO 13485:2003
Light engine and electronics	Design and development	Benchmark Electronics B.V.	ISO 13485:2003
Software app	Design and development	Sogeti Nederland B.V.	ISO 9001:2008

The following table indicates the status of the certificates of the critical subcontractors:

Subcontractor	***Certificate***	***Certificate identification***	***Scope***	***Valid until***	***Issued by***
Benchmark Electronics B.V, Almelo, Netherlands	ISO 13485:2003	1 001 21 48 M P23	The subcontract development and production of non-sterile and non-implantable electromedical devices for delivery to customers which are also product owners.	2015-08-11	UL DQS Inc.
Benchmark Electronics, Brasov, Romania	ISO 13485:2003	1 001 191 5 M P23	The production and servicing of electronic and electromechanical devices for medical use according to customer specifications.	2017-03-01	UL DQS Inc.

Sogeti Nederland	ISO 9001:2008	2074314	Het verlenen van diensten dmv de volgende servicelines: Consultancy, project-, programma- en servicemanagement, implementatie, hosting en beheer van standaard software, analyse en ontwerp van maatwerk applicatie embedded software, infrastructuren, engineering van maatwerk applicatie/embedded software, infrastructuren, beheer van maatwerk applicatie/embedded software, infrastructuren	1-7-2016	DEKRA Certification

The Certification Notice is to be updated with the following information, see TDR19/Ac03.

Company name / address	**Type of service to Manufacturer**	**QS standard and name certifier**	**Certificate number and expiry date**
Benchmark Electronics Romania S.R.L. Parcul Industrial Ghimbav Strada 103C Km2+115 Hala 3 – 507075 Brasov Romania	Production of Blue Touch	ISO 13485:2003 (UL DQS)	10011915 MP23 **(1 March 2017)**

Benchmark Electronics B.V. Lelyweg 10 7602 EA Almelo Netherlands	**Design of light engine and electronics**	**ISO 13485:2003 (UL DQS)**	**1 001 21 48 M P23 (11 August 2015)**
Sogeti Nederland BV Divisies Application New Technology, Application life cycle management, consulting services, infrastructure security & high tech services en software control Lange Dreef 17 4131 NJ Vianen The Netherlands	Design and development mobile phone device app	ISO 9001:2008 **(DEKRA Certification)**	2074314 **(1 June 2016)**

The manufacturer has provided an overview of the production process in a flow chart format in which all important process steps, the quality inspections, tests and the subcontractors are identified.
Clear references have been made to the DMR and relevant procedures or work instructions.

The provided information describes functional testing, however the documentation does not describe specifically what will be part of the final testing, see TDR19/Q13.

The DEKRA reviewer can not yet accept the production information provided by the manufacturer.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q13 Please elaborate on the specific tests that are part of the final testing (e.g. electrical safety tests, functional safety tests)

Response Philips:
Final testing as part of the Benchmark's manufacturing process flow (6.

Manufacturing Information\6.1 Manufacturing Processes) refers to the control plan (6. Manufacturing Information\6.2 Manufacturing conditions).

The final testing includes:

- Mac address verification via Dongle USB to validate Bluetooth feature
- The scanned serial number is programmed into the patch via USB connection

The test specification (Benchmark) has been included for the reviewer's reference.

Electrical safety is elaborated in the Architectural Design (see doc: D000003548 SugarPine Architectural Design in STED folder 2.11.1 General Product Specifications), paragraph 7.3 (insulation diagram). The Means of Operator Protection are placed in the adapter. As a consequence, the adapter shall comply with requirement ADT17 – "The adapter shall comply with IEC60950-1." (see doc: D000002594 SugarPine Adapter Requirements in STED folder 2.11.2 Detailed Product Specifications).

The calibration test and final test procedures are local documents which are available at and controlled by the supplier Benchmark Romania in local language (Romanian). The calibration test is according to Philips instructions as per Software and Calibration manual which has been added for reference in STED folder 5.1 Design Assurance. [Ref. PRP2011_Pain Relief Patch Tester_28062012].

Comments DEKRA:
The provided documents have been reviewed. It was observed that the focus during the final testing is on the optical output of the device. This question is closed.

9 LABELING

Submitted manufacturer's compliance documents:

- 4222_100_3349_1_HR, 2-3-2015
- 4222_100_3350_1_HR, 2-3-2015
- 4222_100_3351_1_HR, 2-3-2015
- 4222_100_3352_1_HR, 2-3-2015
- 4222_100_3353_1_HR, 2-3-2015
- 4222_100_3354_1_HR, 2-3-2015
- PR3840_Quick Start Guide, 21-4-2015
- 4222-100-32601-110-A-box label PR3741 UK
- 4222-100-32601-110-A-box label PR3743 UK
- 4222-100-32601-110-A-box label PR3721 UK
- 4222-100-32601-110-A-box label PR3723 UK
- EU14_XXXX_SUGARPINE US_MUS_F
- EU14_XXXXX_SUGAR PINE-LS-MUS_F
- EU14_XXXXX_SUGAR PINE-LS-PGD_F
- EU14_XXXXX_SUGAR PINE-MUS EXTENSION STRAP_F
- EU14_XXXXX_SUGARPINE US_PGD_F
- MUS XXXX_ SUGARPINE_F
- PGD XXXX_ SUGARPINE_F
- 14160-Consumer_BlueTouch_DL_v3

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 980:2008, Symbols for use in the labeling of medical devices
- EN 1041:2008, Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2012, Medical devices – Symbols to be used with medical labels, labeling and information to be supplied – Part 1: General requirements

Review description and results:

Copy of all labeling

The manufacturer has provided copies of the different labels (device label, primary package label, label on outer package).

The submitted labels for PR 3740 contains the required content. This label shows full compliance to the labeling requirements in the Essential Requirements of the MDD, the requirements described in EN-980, EN 1041 and product standards specific requirements on labels. However some questions were raised, see TDR19/Q14.

Copy of Instructions for Use

The manufacturer has provided a copy of all the manuals and/or inserts which are provided to the users and patients.
The instructions for use contain Intended use, Contra-indications, Important safety information, Warning Electromagnetic emissions and immunity, treatment schedule and treatment modes, Product overview (charging, using, positioning, starting, cleaning), Troubleshooting, Specifications and explanation of symbols.
The IFU shows full compliance to the requirements for Instructions for use in the Essential Requirements of the MDD, the requirements described in EN-1041 and product standards specific requirements on IFU's, except for TDR19/Q15, Q16 and Q17.

The warnings referenced in the instruction for use are sufficiently addressed in the risk management file and vice versa.

Marketing brochures (when available) and applicable website addresses

The manufacturer has provided a copy of all the marketing brochures and website addresses. The claims, intended use and product information are consistent, with the product specifications as described in the instruction for use.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):

TDR19/Q14 The labels as provided gave the following issues:

1. For the reviewer it is unclear which label is used on which position and on which device or accessory.
2. Not all labels could be opened
3. The A-Box labels do not contain CE marking or manufacturer name and address. It could not be verified whether this information is provided on a different label or not.

Response Philips:
1. BOM description including labels was included for your reference
In specific:
- A-box (assembly box) labels are intended for bulk packaging for shipment
- Direction for Use / Quick Start Guide / … are included in the F-box (fancy-box, product packaging for consumer)
- MUS (Make up sheet) and Pos (positions) include label position on the product parts
2. We double checked the files before sending and confirm that they work. If this problem tends to occur again, please do not hesitate to give us a call so we can find another solution.
3. The A-box (assembly-box) is used for shipment and will not reach the customer. The CE marking and manufacturing information is provided on the F-box (fancy-box) which do is intended to be used by the customer.

The serial number format has been updated to comply with EN1041 (as per 2015-05-12, prior to start of production). The format of the serial number is SPYYYY-WW-XXXX, where; YYYY is the year, WW is the week number, XXXX is an unique serial number within the week.

Comments DEKRA:
The provided labels and their position on the device and the packaging was reviewed. The provided documentation is accepted, however the implementation of the manufacturing date clarification will be assessed during the next DEKRA audit at Philips Consumer Lifestyle. This question is closed and action **TDR19/Ac-04** is opened

TDR19/Q15 The PR 3840 quick start guide does not give CE marking or manufacturer name and address, please explain why this is not part of the quick start guide.

Response Philips:
CE marking and manufacturing information is provided on packaging and in DFU. Acknowledged that this information is not available in the Quick Start Guide. As verbally agreed with Paul the team will implement this as a running change. Change request (Ref. CR 1732) has been initiated to update the QSG accordingly.

Comments DEKRA:
The CE mark is sufficiently shown on the device, packaging and IFU.
The display of the CE mark on the Quick Start Guide will be followed-up by action **TDR19/Ac-04**. This question is closed.

TDR19/Q16 No information could be found on how the app is to be installed on a phone (App-store) in the directions for use. Additionally the quick sheet manual only gives compatibility with iOs systems. Is compatibility with Android systems not claimed?.

Response Philips:
Quick start guide for Android is available and has been added to the STED file (was not included before, human error). Acknowledged that DFU does not clearly mention where to download the app. As verbally agreed with Paul the team will implement this as a running change. The team initiated a change request (CR 1732) to update the DFU accordingly.

Comments DEKRA:
The provide Android Quick Start Guide was reviewed and could be accepted. The clarification of the location of the app will be followed-up by action **TDR19/Ac-04**. This question is closed.

TDR19/Q17 The CE marking and the name and address of the manufacturer could not be found as part of the submitted directions for use on a clearly visible position.

1. Why is the CE marking only given as an explanation of the symbols.
2. Why is manufacturing name and address given without harmonized symbol on a non-clearly visible position (why is EN 980 not used)?

Response Philips:
As verbally agreed with Paul the team will place the CE mark and manufacturing information (with EN 980 logo) on a more visible position at the start of the DFU. A change request has been initiated (CR 1732) to implement this running change.

Comments DEKRA:
The improvement of the visibility of the CE mark in the directions for use will be followed-up by action **TDR19/Ac-04**. This question is closed.

10 CONCLUSION OF THIS REPORT

The Notified Body has accepted the technical dossier for the BlueTouch 2.0 and BlueTouch 2.1 for review. The BlueTouch 2.0 and BlueTouch 2.1 have been classified as Class IIa devices. A conformity route according to Annex V + VII of the Council Directive 93/42/EEC is followed.

The initial review of the technical dossier resulted in 1 minor non-conformity, no major non-conformity, and a total of 17 questions.

Table: status review findings.

Review findings that are addressed satisfactorily:	Review findings that need to be addressed before the next DEKRA Notified Body audit:	Review findings that need to be addressed before CE-certification:
TDR19/Q01 - TDR19/Q17 TDR19/R01		

Based on the results of this review, it is concluded that the technical dossier for BlueTouch 2.0 and BlueTouch 2.1 of manufacturer Philips Consumer Lifestyle B.V. does now fulfill the obligations imposed by Annex V + VII of the Medical Device Directive 93/42/EEC. CE-approval of BlueTouch 2.0 and BlueTouch 2.1 is therefore recommended to DEKRA Certification Business Line Medical's Certification Management Board.

DEKRA will need a response to the questions and non-conformities documented in this technical dossier review report. All questions and/or non-conformities need to be addressed satisfactorily.

Action(s):

TDR19/Ac01 **DEKRA:** Upon approval of the BlueTouch 2.0 and BlueTouch 2.1 devices the addendum of CE certificate 2147098CE01 shall be updated in the following way (changes in bold):

- **Blue Touch Pain Relief Patch (Blue LED light)**
- **Blue Touch 2.0 PR3730 (Blue LED light)**
- **Blue Touch 2.1 PR3740 (Blue LED light)**
- Upper back strap PR3721
- Lower back strap PR3723 (including Extension strap PR3723)

TDR19/Ac02 **Philips:** Please submit answers on the findings raised.
Closed

TDR19/Ac03 **DEKRA:** The Certification Notice is to be updated with the following information:

Company name / address	**Type of service to Manufacturer**	**QS standard and name certifier**	**Certificate number and expiry date**
Benchmark Electronics Romania S.R.L. Parcul Industrial Ghimbav Strada 103C Km2+115 Hala 3 – 507075 Brasov Romania	Production of Blue Touch	ISO 13485:2003 (UL DQS)	10011915 MP23 **(1 March 2017)**
Benchmark Electronics B.V. Lelyweg 10 7602 EA Almelo Netherlands	**Design of light engine and electronics**	**ISO 13485:2003 (UL DQS)**	**1 001 21 48 M P23 (11 August 2015)**
Sogeti Nederland BV Divisies Application New Technology, Application life cycle management, consulting services, infrastructure security & high tech services en software control Lange Dreef 17 4131 NJ Vianen The Netherlands	Design and development mobile phone device app	ISO 9001:2008 **(DEKRA Certification)**	2074314 **(1 June 2016)**

TDR19/Ac04 **Philips:** To improve the label, Quick Start Guide and the directions for use in the following way:

1. display of the CE mark on the Quick Start Guide
2. clarification of the location of the app's
3. improvement of the visibility of the CE mark in the directions for use
4. clarification of the manufacturing date on the label

Implementation will be assessed during the next surveillance audit at Philips Consumer Lifestyle in June 2015..

*** END OF REPORT ***

APPENDIX A: DEFINITIONS

The Notified Body review has been carried out in accordance with the relevant requirements of the Conformity Assessment Procedure of the applicable EC-Directive. DEKRA Notified Body distinguishes the following review findings: minor non-conformities, questions and major non-conformities.

Definitions:

Minor non-conformity (R):
A requirement of the applicable EC-Directive has not been fully met. The finding is:
(a) non-systematic; and/or
(b) an isolated occurrence; and/or
(c) not likely to result in the failure of the product performance and/or patient safety.

Major non-conformity (NC):
A requirement of the applicable EC-Directive has not been met. The finding is:
(a) a systematic deviation of the applicable Council Directive; and/or
(b) a failure/deviation that might compromise the performance of the product and/or safety of the patient.

Question:
The reviewed information is not sufficient for the Notified Body to make a statement concerning the status of the finding. Additional information (clarification) from the manufacturer is required. A question has in principle the same status as a major non-conformity and therefore may delay CE-certification.

Observation:
An opportunity for improvement not directly related to a specific requirement of the standard, regulation, quality system and/or MDD/IVDD/AIMDD. Follow up is voluntary and will not further be reviewed by DEKRA.

Corrective actions initial / renewal certification:
The major non-conformity should be corrected and objective evidence of corrective actions taken shall be submitted to the reviewer within 90 days, unless other arrangements have been made and approved.

In the case corrective actions have not been received from the manufacturer within half a year, the review will be stopped and no certification activities will be performed.

Unless stated differently minor non-conformities do hold up certification decisions. Implementation effectiveness of manufacturer's corrective actions will be assessed at the next scheduled audit when appropriate.

Administrative actions:

Assessments of results of corrective action review will be reported.

Version control:

This report is generated through a controlled template, version 1.0.