

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: PHILIPS CONSUMER LIFESTYLE B.V.
Business address: TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS
Medical device(s): Nipple shield SCF153
Classification: Medical Device (Class I)
GMDN code and term: 35337 Nipple Shield, reusable
Scope of application: Products to which the declaration of conformity procedures applies this may include all OR specific or ranges of batches, lots or serial numbers

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied: EN ISO 10993-1:2020
 EN ISO 10993-5:2009
 EN ISO 10993-18:2020
 EN ISO 14971:2019
 EN ISO 15223-1:2016
 EN 1041:2008

Authorised signatory:
Signature



A.Speelman, Senior Compliance Manager Personal Health

September 16, 2021