	Document Name: Declaration of Conformity (DOC) – For Vietnam	Doc#: TFD004-04 Rev#: 01 Page 1 of 1
	NeilMed Wound Wash and Piercing After Care Products	

Manufacturer: NeilMed Pharmaceuticals, Inc.
601 Aviation Blvd., Santa Rosa, CA 95403, United States

European Representative: MDSS GmbH
(according to MDD, 93/42/EEC
Article I, section j) Schiffgraben 41
30175 Hannover
Germany

List of Products:

- NeilMed NeilCleanse Wash 177 mL – 705928652101
- NeilMed Wound Wash 177mL – 705928652019
- NeilMed Wound Wash Antiseptic 75 mL – 705928652071
- NeilMed NeilCleanse Wash 177 mL – 705928652163
- NeilMed Piercing AfterCare Mist Tip 75 mL – 705928652750
- NeilMed WW Piercing After Care 177 mL - with mist tip – 705928652057

Classification: Class IIA; MDD – Annex IX (Rule 4)

Conformity Assessment Route: Annex II (excluding Section 4) of Directive 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the council Directive 93/42/EEC as amended by 2007/47/EC for medical devices as transposed into national law, which apply to them. The applied standard quality management system meets requirements of EN ISO 13485:2012. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

- EN ISO 13485:2012
- EN ISO 14971:2012
- EN ISO 10993-1:2009/ AC:2010
- ISO 15223-1:2012
- EN 1041:2008


Notified Body: TUV SUD Product Service
GmbH Zertifizierstelle
Ridlerstrasse 65, 80339 Munchen, Germany

Notified Body Number: 0123

(EC) Certificate(s): G1 066204 0012 Rev 00

Place & Date of Original Issue: Santa Rosa, CA 95403, USA; 2012-04-19

Place & Date of Current Issue: Santa Rosa, CA 95403, USA; 2018-09-05

Signature & Date:  06/13/2022

Dinesh Patel (VP of Manufacturing Operations)