DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Chemische Fabrik Dr. Weigert GmbH & Co. KG
Mühlenhagen 85
D-20539 Hamburg

I, Mr Bernd Stranghöner, CEO, hereby declare that the below mentioned medical device:

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rule of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices regulation 2012.

(A) Particulars of medical device

Generic name: neodisher ® IR
Specified name: neodisher ® IR
Brand/model: Dr. Weigert
Manufacturer: Chemische Fabrik Dr. Weigert GmbH & Co. KG
Country of origin: Germany
Manufacturing site: Mühlenhagen 85, D-20539 Hamburg

Risk-based classification:

Class A, Rule 4 (All other non-invasive devices are in class A)

Classification rule: Rule 4

GMDN Code: 41654

Definition:

Detergent for the dishwasher. Has cleaning and possibly antimicrobial properties through a surface effect on the dishes and cutlery to be cleaned. After use, the product can not be reused.

(B) Quality Management System Certificate ("QMS"):

DQS Medizinprodukte GmbH

Certificate number: 001549 MP2016

Issuance date: 2021-03-26

Expire date: 2024-03-25

(C) Standards Applied:

DIN EN ISO 13485:2016 + AC:2018+A11:2021 Medical devices – Quality Management Systems – Requirements for regulatory purposes

ISO 9001:2015 Quality Management Systems – Requirements

DIN EN ISO 15223-1:2021-07 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

DIN EN ISO 14971:2019 Medical devices – Application of risk management to medical devices

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 21/12/2021.

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Date: 21/12/2021

Authorised Signatory:

Hamburg, 06. 01. 2022
Date

Name, Position
B. Stranghöner, CEO