č.ZP/14/02/2019

schülke

EC DECLARATION OF CONFORMITY

According to Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

DECLARATION OF CONFORMITY

Medical Device	**desam® effekt +**
Product group	Disinfection
Model	1l , 5l
Classification Acc. To Directive 93/42/EEC, Annex IX	IIa
Producer	Schulke CZ, s.r.o. Lidická 445 735 81 Bohumín, The Czech Republic
Notified Body	Institute for testing and Certification, Inc. Tř. Tomáše Bati 299, Louky 763 02 Zlín, The Czech Republic Ident.No.: **1023**
Issued CE certificate	No. 190229QS/NB
Standards applied	**COUNCIL DIRECTIVE 93/42/EEC** of 14 June 1993 concerning medical devices, Annex No.1 Government Order No. 54/2015 Coll., on the technical requirements for medical devices ***EN ISO 13485*** Medical devices — Quality management systems — Requirements for regulatory purposes ***EN ISO 14971*** Medical devices -- Application of risk management to medical devices ***EN ISO 15223-1*** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements ***EN 1041- a1*** Information supplied by the manufacturer of medical devices **EN ISO 14885** - Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics

Digitally signed by Gritaenco Andrei
Date: 2022.12.26 16:36:55 EET
Reason: MoldSign Signature
Location: Moldova

We herewith declare that madical device class IIa is complaint with specific requirements of the Directive 93/42/EEC annex II point 3.2

Bohumín, 2020-03-23

Dr. Viktória Procházková
Executive

Jarmila Fafílková
Quality and Regulatory Affairs Manager

Declration is valid until an update version has been issued, but not longer than 2024-05-08