č.ZP/12/06/2015

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 | **chirosan® plus** |
| Product group | Disinfection |
| GMDN | 47631 |
| Classification<br>Acc. To Directive 93/42/EEC,<br>Annex IX | IIb |
| Producer | Schulke CZ, s.r.o.<br>Lidická 445<br>735 81 Bohumín, The Czech Republic |
| Notified Body | Institute for testing and Certification, Inc.<br>Tř. Tomáše Bati 299, Louky<br>763 02 Zlín, The Czech Republic<br>Ident.No.: **1023** |
| Issued CE certificate | No. 19 0229 QS/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<br>***EN ISO 13485*** Medical devices — Quality management systems — Requirements for regulatory purposes<br>***EN ISO 14971*** Medical devices -- Application of risk management to medical devices<br>***EN ISO 15223-1*** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements<br>***EN 1041- a1*** Information supplied by the manufacturer of medical devices<br>**EN ISO 14885** - Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics |

Digitally signed by Grițaenco Andrei
Date: 2022.12.26 15:51:47 EET
Reason: MoldSign Signature
Location: Moldova

We herewith declare that madical device class IIb is complaint with specific requirements of the Directive 93/42/EEC annex II (without point IV) concerning medical devices

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*