Declaration of Conformity

Manufacturer:	Scarpro N.V. Lobulckstraat 3 9880 Aalter Belgium
Manufacturer SRN:	BE-MF-000001477
Product:	**Silicone Gel**
Product identification:	Basic UDI-DI – 5413698110008YV See appendix I for tradenames and product UDI-DI
Risk class:	Class 1 Medical Device, based on rule 4 of Annex VIII

We, Scarpro N.V., hereby declare and confirm that the Silicone Gel products that are covered by this declaration are in conformity with EU regulation 2017/745 .

This declaration of conformity is issued under the sole responsibility of Scarpro N.V. and supported by the Quality System certification based on ISO 13485:2016, quality system certificate with reference number 11448 A - M, first issued on 28 May 2014, delivered by KIWA CERMET ITALIA, SpA.

This declaration is no longer valid if any change on the products will be made without our written confirmation.

Date, February 14th 2022

SCARPRO N.V.
Lobulckstraat 3
9880 Aalter, Belgium
A BAP-Medical Company

Irene Körbl
RA Manager
Scarpro N.V.

Appendix I

Silicone Gel			
PRODUCT NAME	**PRODUCT CODE**	**PACKAGING**	**UDI-DI**
SCARBAN Velvet Touch	4103015	15ml	05413698110015

Date, February 14th 2022

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Irene Körbl
RA Manager
Scarpro N.V.