

EC DECLARATION OF CONFORMITY

Manufacturer: NAQI nv
Stadsbeemd 1037
B-3545 Halen
Belgium

Manufacturer SRN: BE-MF-000001241

Devices: Silicone gels

Basic UDI-DI: 542502989STUJ

Device codes:

Device name	Device code	UDI-DI (GS1 GTIN)
Silicon Touch	ST15	05425029890145
Velvet Touch	SPVT015	05425029892590

Intended purpose: Silicone gels used for scar management.

Risk class: Class I Medical device based on rule 1 MDR 2017/745 Annex VIII

We, NAQI NV, hereby declare and confirm, under our sole responsibility as manufacturer, that the devices covered by this declaration are in conformity with the requirements of EU regulation 2017/745.

Date : 01/10/2021

Name and function: E. M. Geyskens CEO of NAQI

Signature

