EU declaration of conformity

We, the company

Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Straße 4
50769 Cologne
Germany

declare as manufacturer, SRN: DE-MF-000005577 in sole responsibility, that the products listed from page 2 onwards of the

Product group: 1.3 Articulating Silk
Basic UDI-DI: ++E2101x3xSilkx80TS

meet the applicable requirements of Regulation (EU) 2017/745 on medical devices and the subsequent regulations and standards:

Regulation (EU) 2017/745
EN 10993-1:2020
EN 14971:2019
EN 62366:2015 + AC:2015 + A1:2020

The technical documentation proving compliance with the requirements of the above-mentioned regulations and standards is documented in the Development File and Medical Devices File parts of the technical file and is available to the National Competent Authorities.

This declaration of conformity is valid from: 2021-10-25.

Signed by: André Bausch
Authority: General Manager of Dr. Jean Bausch GmbH & Co. KG

Date of signature: 2021-10-25
Place of signature: Cologne - Germany

Digitally signed by Smîntînă Alexandru
Date: 2022.07.29 16:29:32 EEST
Reason: MoldSign Signature
Location: Moldova

Form
EU declaration of conformity (DoC)

Bausch
WE MAKE OCCLUSION VISIBLE

REF	UDI-DI	Product / Package	Content	Color	Version / LOT/SN (from ... to)	Classification, acc. to Annex VIII Rule(s)	Class	Conformity assessment procedure, acc. to (EU) 2017/745
BK 06	+E210BK0609	Silk ribbon 80 microns, 80 mm wide	3 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 07	+E210BK070A	Silk ribbon 80 microns, 16 mm wide	10 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 08	+E210BK080B	Silk ribbon 80 microns, 16 mm wide	10 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 876	+E210BK8760O	Silk ribbon 80 microns, 80 mm wide	3 m	green	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 877	+E210BK8770P	Silk ribbon 80 microns, 80 mm wide	3 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III