

EC Declaration of Conformity

Manufacturers Name: Blue Medical B.V.

Manufacturers Address: Sluispolderweg 79, 1505HJ, Zaandam, The Netherlands

SRN (Single Registration Number): NL-MF-000010818

UDI-DI: See reference list in attachment.

Name of the Device (s): **AP | Instrument Protector**

Product (group) code (s): BM330025**, BM3300259*

Classification: CLASS I Medical Device

Conformity assessment route:

Instrument Protector has been classified as Class I according to Annex VIII rule 1, and is in conformity with the general safety and performance requirements (Annex I) and provisions of the Regulation MDR 2017/745

and (are)(is) in conformity with the relevant harmonized standards:

- ISO 11607-1:2020
- ISO 14971:2019
- ISO 15223-1:2021
- ISO 13485:2016

and is subject to the procedure set out in Annex II & III of the Regulation MDR 2017/745.

This Declaration of Conformity is issued under the sole responsibility of Blue Medical B.V.. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Mr. Alex Welleweerd
Sales Director

Place, date (dd.mm.yyyy) of issue and version:

Zaandam, 24.11.2022, v6

Attachment to Declaration of Conformity

Productname	Article reference	UDI-DI (GTIN)	Classification
AP Instrument Protector small – 100 pcs	BM33002580	8720174715631	1 (rule 1)
AP Instrument Protector medium – 100 pcs	BM33002585	8720174715648	1 (rule 1)
AP Instrument Protector mini – 100 pcs	BM33002590	8720174715655	1 (rule 1)
AP Instrument Protector 56mm x 86mm – 100 pcs	BM33002595	8720174715662	1 (rule 1)