

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 | Sterilization pen**

Product (group) code (s): BM330050**

Classification: Non-Medical Device

Conformity assessment route:

The Sterilization Pen has not been classified as Class I according to Annex VIII rule 1, and therefore does not need to be in conformity with the general safety and performance requirements (Annex I) and provisions of the Regulation MDR 2017/745.

The product(s) however (are)(is) in conformity with the relevant harmonized standards:

- EN 15223-1:2021
- ISO 13485:2016

and is not 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 Non-Medical Device(s) specified above cannot 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:



Ms. Monique Buijsman
Operations Manager

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

Zaandam, 08.03.2022, v4

Attachment to Declaration of Conformity

Productname	Article reference	UDI-DI (GTIN)	Classification
AP Sterilization pen black	BM33005028	8720174715808	Non-Medical Device
AP Sterilization pen blue	BM33005030	8720174715815	Non-Medical Device