

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): **CP | Helix Test System**

Product (group) code (s): BM3300203*

Classification: Non-Medical Device

Conformity assessment route:

The Helix Test System 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:

- ISO 11140-1:2014 (Type 2)
- EN 867-5:2001
- ISO 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, v5

Attachment to Declaration of Conformity

Productname	Article reference	UDI-DI (GTIN)	Classification
CP Helix Test System 3.5 min - 100 pcs	BM33002030	8720174715358	Non-Medical Device
CP Helix Test System 3.5 min - 400 pcs	BM33002031	8720174715365	Non-Medical Device
CP Helix Test System 5.3 min - 100 pcs	BM33002032	8720174715372	Non-Medical Device
CP Helix Test System 7 min - 100 pcs	BM33002034	8720174715389	Non-Medical Device
CP Helix Test System 18 min - 250 pcs	BM33002036	8720174715396	Non-Medical Device