Declaration of Conformity

for Benchmark Medical Face Masks

Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

This EU declaration of conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in Regulation (EU) 2017/745, and other applicable Union legislation as listed in Annex 1 to this declaration, have been fulfilled in relation to the devices listed in Annex 3 to this declaration.

General Product Name:	Medical Face Masks
Legal Manufacturer: (Name on Label)	**Globus (Shetland) Ltd.** T2 Trafford Point, Twining road, Trafford Park, Manchester, M17 1SH, UK
Product Name:	Benchmark Medical Face Masks
Product Codes or Catalogue Numbers:	See Appendix 3
Intended Purpose:	Protect health professionals during medical procedures to prevent airborne transmission of infections in patients and the treating personnel.
Risk Class	Class I
Classification Rule:	Rule 1
Sterile:	No
Measuring Function:	No
Reusable:	No
Common Specifications (CS):	As per Annex 2 – Device Listing
Notified Body:	N/A
Conformity Assessment Procedure:	Article 19, Annex II and Annex III.
Certificate Type(s) and Reference Number(s):	N/A

Additional Information:	None
EU Authorised Representative:	**Globus EMEA Ltd.** 51 Dawson St, Dublin, DO2 AN25, Ireland

Position: Regulatory & Quality Director Date: 15h October 2021

Who is, or has been delegated the task of ensuring compliance of the devices by, the person responsible for regulatory compliance of the manufacturer.

Appendix I – Union Legislation

The devices listed in Annex 3 are in conformity with the following Union legislation:

- Regulation (EU) 2017/745

Appendix 2 – Common Specifications (CS) and Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices Part 1: Evaluation and testing
EN 14683:2019	Medical face masks. Requirements and test methods
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments. Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

There are currently no CS's which apply to this device.

Appendix 3 – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
BMR00001DZ	Benchmark Medical face mask with earloops	35177

Version History

Version	Compiled By	Date	Description
1	Christian Halford	19 Feb 2021	First Issue