

Declaration of Conformity

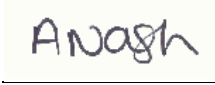
Sigma Transwab®

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.
In addition, Article 120 (3) of Regulation (EU) 2017/745 (MDR)

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Sigma Transwab®
Legal Manufacturer:	Medical Wire & Equipment Co. (Bath) Ltd Potley Lane, Corsham, Wiltshire, United Kingdom
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	Sample collection and Transport Device
MDD Classification:	Is
Notified Body:	SGS 1639
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Production Quality Assurance outlined in Annex V

Name Amanda Nash **Position** QA / RA Manager

Signed  **Date** 25/05/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

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

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	UDI-DI	GMDN
MW177S	Sigma Transwab®	05060259070242	62773
MW177PF	Sigma Transwab®	05060259073595	62773
MW178PF	Sigma Transwab®	05060259073618	62773
MW177HF	Sigma Transwab®	05060259073588	62773
MW178HF	Sigma Transwab®	05060259073601	62773
MW177S2ML	Sigma Transwab®	05060259070457	62773
501005	Sigma Transwab®	05060259076043	62773
501006	Sigma Transwab®	05060259076053	62773
501007	Sigma Transwab®	05060259076060	62773
MW179SF	Sigma Transwab®	05060259076145	62773
M200141	U-SWAB™ MRSA Triple	05060259076350	62773
M200142	U-SWAB™ MRSA Double	05060259076367	62773

Version History

Version	Compiled by	Date	Description
1.0	Amanda Nash	17/02/20	First issue.
2.0	Amanda Nash	22/03/21	2 nd addition Removed a part code.
3.0	Amanda Nash	13/07/2021	3 rd Issue. Added Article 120(3) and updated date of ISO 14971.
4.0	Amanda Nash	07/07/2022	4 th Issue. Added part number.
5.0	Amanda Nash	29/09/2022	5 th Issue. Removed a part number.
6.0	Amanda Nash	18/04/2023	6 th issue added new part codes.

6.1	Amanda Nash	11/05/2023	6 th issue corrected a typo in the part code.
7.0	Amanda Nash	04/01/2023	7 th issue added UDI-DI
8.0	Camelia Horvath	07/08/2025	8 th issue new products added