

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:	Ila
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
MW167S	Sigma Transwab®	05060259070181	62773
MW176S	Sigma Transwab®	05060259070198	62773
MW176S2ML	Sigma Transwab®	05060259072628	62773
MW176SE2	Sigma Transwab®	05060259070204	62773
MW176S3	Sigma Transwab®	05060259070211	62773
MW176PF	Sigma Transwab®	05060259073540	62773
MW176HF	Sigma Transwab®	05060259073533	62773
MW176SE23ML	Sigma Transwab®	05060259073564	62773
MW176S3ML	Sigma Transwab®	05060259075995	62773
501001	Sigma Transwab®	05060259076022	62773
501002	Sigma Transwab®	05060259076039	62773
350022	Sigma Transwab®	05060259076138	62773
MW167SF	Sigma Transwab®	05060259075483	62773

Version History

Version	Compiled by	Date	Description
1.0	Amanda Nash	23/07/19	First issue.
2.0	Amanda Nash	17/02/20	2 nd issue Update classification and CE Number
3.0	Amanda Nash	22/03/21	Added additional part code.
4.0	Amanda Nash	13/07/2021	4th Issue. Added Article 120(3) and updated date of ISO 14971.
5.0	Amanda Nash	07/07/2022	5th Issue. Added part number.
6.0	Amanda Nash	18/10/2022	6 th issue added part number.

7.0	Amanda Nash	18/04/2023	7 th issue added new part codes.
8.0	Amanda Nash	04/01/2024	8 th issue added UDI-di
9.0	Camelia Horvath	16/05/2024	9 th issue product discontinuation
10.0	Camelia Horvath	30/08/2024	10 th issue added new part code