



EU Declaration of Conformity

Date: 05/05/2023

Declaration of Conformity

for Sigma Transwab®

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

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

General Product Names:	Sigma Transwab® including VCM, Virocult, TSB, GBS,
Manufacturer:	Medical Wire & Equipment Co. (Bath) Ltd Potley Lane, Corsham, Wiltshire, United Kingdom
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	Patient sample collection device.
Intended User:	Professional use,
IVD Directive Category:	General
Notified Body:	N/A
IVD Directive Assessment route:	Self-declaration after fulfilling the requirements in Annex III.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar BKR 4013 Malta

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

Signed Anagh **Date** 05/05/2023

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 his own name, regardless of whether these operations are carried out by the Manufacturer, or on their 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
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
ISO 18113-1:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MW860	Sigma Transwab®	62773
MW176M	Sigma Transwab®	62773
MW176T3	Sigma Transwab®	62773
MW915T	Sigma VCM	62773
MW916T	Sigma VCM	62773
MW926T	Sigma VCM	62773
MW950T	Sigma Virocult	62773
MW951T	Sigma Virocult	62773
MW951T3	Sigma Virocult	62773
MW951T15	Sigma Virocult	62773
MW168T	Sigma Transwab®	62773
MW268T	Sigma Transwab®	62773
MWGBST	Sigma GBS	62773
MWTSB65T	Sigma TSB	62773

Version History

Version	Compiled by	Date	Description
1.0	A Nash	10/06/19	First issue
2.0	A Nash	24/07/19	Second Issue
3.0	A Nash	19/02/20	Third issue
4.0	A Nash	09/11/20	Forth Issue
5.0	A Nash	24/08/2021	Fifth issue
6.0	A Nash	05/05/2023	Updating the Regulatory Section