



EU Declaration of Conformity

Version: 8.0

Date: 04/01/2024

Declaration of Conformity

Sigma Virocult®

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 Virocult®
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:	Class 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
MW950S	Sigma Virocult®	05060259070495	62773
MW950S2	Sigma Virocult®	05060259070501	62773
MW950S3	Sigma Virocult®	05060259070518	62773
MW950S3B	Sigma Virocult®	05060259074776	62773
MW950S3ML	Sigma Virocult®	05060259072703	62773
MW950SENT	Sigma Virocult®	05060259070525	57937
MW950SE2	Sigma Virocult®	05060259070532	57937
MW952H23ML	Sigma Virocult®	05060259074868	62773
MW951S	Sigma Virocult®	05060259070556	62773
MW951S2ML	Sigma Virocult®	05060259072604	62773
MW951S2	Sigma Virocult®	05060259072598	62773
MW951SENT	Sigma Virocult®	05060259070563	57937
MW951SENT2ML	Sigma Virocult®	05060259074837	57937
MW951SE23ML	Sigma Virocult®	05060259074820	57937
MW951SE2	Sigma Virocult®	05060259072611	57937
MW951PF2ML	Sigma Virocult®	05060259074806	62773
MW951PFENT1ML	Sigma Virocult®	05060259070907	57937
MW951S3ML	Sigma Virocult®	05060259074813	62773
MW951HF	Sigma Virocult®	05060259075650	62773
501351	Sigma Virocult®	05060259076077	62773
501355	Sigma Virocult®	05060259076084	62773

Version History

Version	Compiled by	Date	Description
1.0	Amanda Nash	13/06/19	First issue.
2.0	Amanda Nash	24/07/19	Second Issue
3.0	Amanda Nash	17/02/20	3 rd issue Updated CE Number
4.0	Amanda Nash	07/05/20	4 th issue additional product codes.
5.0	Amanda Nash	10/06/2022	5 th issue addition of Article 120 and additional product codes.
6.0	Amanda Nash	18/04/2023	6 th issue added new part codes.
7.0	Amanda Nash	03/08/2023	7 th issue removed discontinued part codes.
8.0	Amanda Nash	04/01/2024	8 th issue added UDI-DI