



EU Declaration of Conformity

Version: 13.0

Date: 20/02/2025

Declaration of Conformity

Sigma VCM™

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 VCM™
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 ANash **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
MW910S	Sigma VCM™	05060259070587	62773
MW911S	Sigma VCM™	05060259072094	57937
MW911S3ML	Sigma VCM™	05060259076169	57937
MW912S	Sigma VCM™	05060259070600	57937
MW918S	Sigma VCM™	05060259070631	62773
MW919S	Sigma VCM™	05060259070648	57937
MW920S	Sigma VCM™	05060259070655	57937
MW921S	Sigma VCM™	05060259070662	62773
MW924S	Sigma VCM™	05060259070679	62773
MW910PF2ML	Sigma VCM™	05060259074660	62773
MW911PF2ML	Sigma VCM™	05060259074691	57937
MW911PF3ML	Sigma VCM™	05060259076244	57937
MW910HF2ML	Sigma VCM™	05060259075582	62773
MW911HF2ML	Sigma VCM™	05060259075599	57937
MW919PF	Sigma VCM™	05060259079733	57937
MW910S3ML	Sigma VCM™	05060259072970	62773
MW913PF2ML	Sigma VCM™	05060259076770	57937
MW914PF2ML	Sigma VCM™	05060259079955	57937
501701	Sigma VCM™	05060259076091	57937
501706	Sigma VCM™	05060259076114	57937
501702	Sigma VCM™	05060259076107	57937
M400010	Sigma VCM™	05060259072888	57937
M350101	Sigma VCM™	05060259075735	57937
M350102	Sigma VCM™	05060259075742	57937
M350103	Sigma VCM™	05060259075759	57937

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 Update CE Number
4.0	Amanda Nash	17/03/21	4th issue Added new part number
5.0	Amanda Nash	17/02/22	5th issue Added new part number
6.0	Amanda Nash	08/07/2022	6th issue Added new part numbers
7.0	Amanda Nash	18/04/2023	7 th issue added new part codes.
8.0	Camelia Horvath	11/07/2023	8 th issue added new part number
9.0	Amanda Nash	04/01/2024	9 th issue added UDI-DI
10.0	Camelia Horvath	22/08/2024	10 th issue added a new part number
11.0	Camelia Horvath	29/08/2024	11 th issue added a new part number
12.0	Camelia Horvath	29/08/2024	12 th issue added a new part number
13.0	Camelia Horvath	20/02/2025	13 th issue added a new part number