



Declaration of Conformity

Dryswab™

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:	Dryswab™ Sigma Swab®
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	Classification	GMDN
I2500I	Dryswab™	05060259076190	Is	33722
32500I	Dryswab™	05060259075919	Is	33722
325002	Dryswab™	05060259075926	Is	33722
325003	Dryswab™	05060259075933	Is	33722
325004	Dryswab™	05060259075940	Is	33722
325005	Dryswab™	05060259076206	Is	33722
325006	Dryswab™	05060259076213	Is	33722
MW010	Dryswab™	05060259079849	Is	33722
MW011	Dryswab™	05060259079832	Is	33722
MW012	Dryswab™	05060259079825	Is	33722
MW013	Dryswab™	05060259079818	Is	33722
MW015	Dryswab™	05060259079801	Is	33722
MW100	Dryswab™	05060259070860	Is	33722
MW1028	Dryswab™	05060259070877	Is	33722
MW1028D	Dryswab™	05060259070891	Is	33722
MW1048	Dryswab™	05060259070921	Is	33722
MW1048J	Dryswab™	05060259070938	Is	33722
MW108	Dryswab™	05060259070723	Is	33722
MW108/10	Dryswab™	05060259070754	Is	33722
MW108/2	Dryswab™	05060259070730	Is	33722
MW108/20	Dryswab™	05060259070761	Is	33722
MW108/5	Dryswab™	05060259070747	Is	33722
MW112	Dryswab™	05060259070792	Is	33722
MW112/2	Dryswab™	05060259070396	Is	33722
MW112/2D	Dryswab™	05060259072994	Is	33722

MW112BP	Dryswab™	05060259075476	Is	33722
MW112D	Dryswab™	05060259070808	Is	33722
MW113	Dryswab™	05060259073021	Is	33722
MW130	Dryswab™	05060259070952	Is	33722
MW142	Dryswab™	05060259070983	Is	33722
MW146	Dryswab™	05060259071102	Is	33722
MW147	Dryswab™	05060259071119	Is	33722
MW148	Dryswab™	05060259071126	Is	33722
MW151	Dryswab™	05060259070822	Is	33722
MW151D	Dryswab™	05060259073137	Is	33722
MW155	Dryswab™	05060259070853	Is	33722
MW160	Dryswab™	05060259070990	Is	33722
MW809	Dryswab™	05060259076008	Is	33722
MW810	Dryswab™	05060259074448	Is	33722
MW811	Dryswab™	05060259074462	Is	33722
MW812	Dryswab™	05060259074486	Is	33722
MW813	Dryswab™	05060259074493	Is	33722
MW814	Dryswab™	05060259074523	Is	33722
MW816	Dryswab™	05060259072468	Is	33722
MW817	Dryswab™	05060259072482	Is	33722
MW818	Dryswab™	05060259074561	Is	33722
MW819	Dryswab™	05060259072512	Is	33722
MW820	Dryswab™	05060259074592	Is	33722
MW821	Dryswab™	05060259074615	Is	33722
MW822	Dryswab™	05060259074639	Is	33722
MW830	Dryswab™	05060259072635	Is	33722
MW831	Dryswab™	05060259072642	Is	33722
MW832	Dryswab™	05060259072673	Is	33722
MW833	Dryswab™	05060259072659	Is	33722
MW834	Dryswab™	05060259072666	Is	33722
MW836	Dryswab™	05060259072543	Is	33722
MW837	Dryswab™	05060259072550	Is	33722
MW838	Dryswab™	05060259072567	Is	33722
MW839	Dryswab™	05060259072680	Is	33722
MW840	Dryswab™	05060259072697	Is	33722
MW940	Sigma Swab®	05060259070389	Is	33722
MW940/79	Sigma Swab®	05060259070884	Is	33722
MW941	Sigma Swab®	05060259070402	Is	33722
MW943	Sigma Swab®	05060259070433	Is	33722

MW944	Sigma Swab®	05060259070440	Is	33722
MW946	Sigma Swab®	05060259070488	Is	33722
M200101	U-SWAB™ VAGINAL	05060259076374	Is	33722

Version History

Version	Compiled by	Date	Description
1.0	Amanda Nash	13/06/2019	First issue.
2.0	Amanda Nash	24/07/2019	2 nd issue following Classification review
3.0	Amanda Nash	11/09/2019	3 rd Issue
4.0	Amanda Nash	17/02/2020	4 th issue updated CE number
5.0	Amanda Nash	19/05/2020	5 th issue update product codes
6.0	Amanda Nash	12/01/2021	6 th issue update product codes
7.0	Amanda Nash	19/05/2021	7 th issue Updated product codes
8.0	Amanda Nash	28/06/2021	8 th issue Updated standard section
9.0	Amanda Nash	31/05/2022	9 th issue Updated product codes.
10.0	Amanda Nash	07/07/2022	10 th issue Updated product codes.
11.0	Amanda Nash	18/10/2022	11 th issue Updated product codes.
12.0	Camelia Horvath	11/07/2023	12 th issue Updated product codes.
13.0	Amanda Nash	03/08/2023	13 th issue removed discontinued product codes.
14.0	Amanda Nash	05/01/2024	14 th issue added UDI and removed discontinued items.
15.0	Camelia Horvath	20/02/2025	15 th issue Updated product codes.
16.0	Camelia Horvath	07/08/2025	16 th issue Adding a new product