

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

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/Compliance Manager

Signed  **Date** 19/05/21

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 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	Classification	GMDN
MW940I25	Sigma Swab™	Is	33722
MW940	Sigma Swab™	Is	33722
MW943I25	Sigma Swab™	Is	33722
MW943	Sigma Swab™	Is	33722
MW944I25	Sigma Swab™	Is	33722
MW944	Sigma Swab™	Is	33722
MW945I25	Sigma Swab™	Is	33722
MW945	Sigma Swab™	Is	33722
MW94I	Sigma Swab™	Is	33722
MW942	Sigma Swab™	Is	33722
MW946	Sigma Swab™	Is	33722
MWI12	Dryswab™	Is	33722
MWI12D	Dryswab™	Is	33722
MWI12BP	Dryswab™	Is	33722
MWI13I25	Dryswab™	Is	33722
MWI13I250	Dryswab™	Is	33722
MWI5I	Dryswab™	Is	33722
MWI5ID	Dryswab™	Is	33722
MWI55	Dryswab™	Is	33722
MWI00	Dryswab™	Is	33722
MWI02I	Dryswab™	Is	33722
MWI028	Dryswab™	Is	33722
MWI02ID	Dryswab™	Is	33722
MWI028D	Dryswab™	Is	33722

MW104I	Dryswab™	Is	33722
MW1048	Dryswab™	Is	33722
MW104IJ	Dryswab™	Is	33722
MW1048J	Dryswab™	Is	33722
MW130	Dryswab™	Is	33722
MW142	Dryswab™	Is	33722
MW160	Dryswab™	Is	33722
MW810	Dryswab™	Is	33722
MW810I25	Dryswab™	Is	33722
MW811	Dryswab™	Is	33722
MW811I25	Dryswab™	Is	33722
MW812	Dryswab™	Is	33722
MW812I25	Dryswab™	Is	33722
MW813	Dryswab™	Is	33722
MW813I25	Dryswab™	Is	33722
MW814	Dryswab™	Is	33722
MW814I25	Dryswab™	Is	33722
MW830	Dryswab™	Is	33722
MW831	Dryswab™	Is	33722
MW832	Dryswab™	Is	33722
MW833	Dryswab™	Is	33722
MW834	Dryswab™	Is	33722
MW816	Dryswab™	Is	33722
MW816I25	Dryswab™	Is	33722
MW817	Dryswab™	Is	33722
MW817I25	Dryswab™	Is	33722
MW818	Dryswab™	Is	33722
MW818I25	Dryswab™	Is	33722
MW819	Dryswab™	Is	33722
MW819I25	Dryswab™	Is	33722
MW820	Dryswab™	Is	33722
MW820I25	Dryswab™	Is	33722
MW821DC	Dryswab™	Is	33722
MW821I25	Dryswab™	Is	33722
MW822I25	Dryswab™	Is	33722
MW836	Dryswab™	Is	33722
MW837	Dryswab™	Is	33722
MW838	Dryswab™	Is	33722
MW839	Dryswab™	Is	33722

MWI08	Dryswab™	Is	33722
MWI08/2	Dryswab™	Is	33722
MWI08/5	Dryswab™	Is	33722
MWI08/10	Dryswab™	Is	33722
MWI08/20	Dryswab™	Is	33722
MWI09	Dryswab™	Is	33722
MWI47	Dryswab™	Is	33722
MWI48	Dryswab™	Is	33722
MW840	Dryswab™	Is	33722
MW010	Dryswab™	Is	33722
MW011	Dryswab™	Is	33722
MW012	Dryswab™	Is	33722
MW013	Dryswab™	Is	33722
MW001LF	Dryswab™	Is	33722
MW002NF	Dryswab™	Is	33722
MW015	Dryswab™	Is	33722

Version History

Version	Compiled by	Date	Description
1.0	Amanda Nash	13/06/19	First issue.
2.0	Amanda Nash	24/07/19	2 nd issue following Classification review
3.0	Amanda Nash	11/09/19	3 rd Issue
4.0	Amanda Nash	17/02/20	4 th issue updated CE number
5.0	Amanda Nash	19/05/20	5 th issue update product codes
6.0	Amanda Nash	12/01/21	6 th issue update product codes
7.0	Amanda Nash	19/05/21	7 th issue Updated product codes