Declaration of Conformity

for SAMPLE CONTAINERS

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Sample Containers
Basic UDI-DI:	3877000524MC47775XE
SRN:	BA-MF-000009145
Manufacturer:	MA-COM d.o.o., Gospodarsko-poslovna zona Hodovo bb 88360 Stolac, BiH
Variants:	If any - as per Appendix II – Product Listing/Schedule
Intended Use:	Devices are intended for the non-sterile, safe collection, storage and transport of human biological specimens for laboratory analysis.
Intended User:	It can be used by laymen, laboratory technicians, medical or pharmaceutical professionals and everyone else depending on the specific purpose and type of samples they are used for
IVD Regulation Classification:	Class A [Rule 5]
Conformity Assessment Route	In accordance with Article 48 of IVDR 2017/746, Declaration of Conformity according to Article 17 after preparation of the technical documentation in Annexes II and III.
Certificated body	DNV - Business Assurance
Certificate Reference:	ISO 13 485: 2016 -212433-2017-AQ-HRV-ACCREDIA
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Representative SRN:	MT-AR-000000234
CH Authorised representative	QS Experts AG, Rütihof 1, CH-8820 Wädenswil, Switzerland
CH Authorised representative SRN:	CHRN-AR-20000145
IVD regulation Assessment Route:	In accordance with Article 48 of IVDR 2017/746, for Class A, non-sterile product, Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III.

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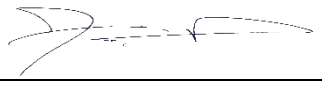
Name:	Ivica Vrljičak	Role:	General director		
Signature:		Date	11.9.2026	Place	STOLAC, BOSNIA AND HERZEGOVINA

Who is the natural and legal person who is responsible for the design, manufacture, packaging and labeling before the device is placed on the market under his own name, regardless of whether these actions are carried out by the Manufacturer or by a third party on its behalf.

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Appendix I -Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 10993-1:2025	*Biological evaluation of medical devices*
EN ISO 6717:2021	In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood
EN ISO 18113-1:2022	In vitro diagnostic medical devices - Information supplied by themanufacturer (labelling) - Part 1: Terms, definitions and generalrequirements
ISO 2859-1:1999	Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
IEC 62366-1:2015/Amd 1:2020	Medical devices Part 1: Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
MDCG 2020-16 rev.5	*Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746*
MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)

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Appendix II – Product Listing/Schedule

Catalogue Number	Description/Name	GMDN Code	EMDN CODE	UDI-DI
1340	General specimen container IVD, no additive, non-sterile, 100 ml, green lid	47775	W0580	03877000524181
1546	General specimen container IVD, no additive, non-sterile, 100 ml, red lid	47775	W0580	03877000524655
1342	General specimen container IVD, non-sterile, 100 ml, with green screw lid – 4 × 100 pcs	47775	W0580	03877002407208
1340-50	General specimen container IVD, non-sterile, 100 ml, with green screw lid – 7 × 50 pcs	47775	W0580	03877002407277
1340-CR	General specimen container IVD, no additive, non-sterile, 100 ml, green lid, clean room produced and packaged	47775	W0580	03877000524662
1546-CR	General specimen container IVD, no additive, non-sterile, 100 ml, red lid, clean room produced and packaged	47775	W0580	03877000524990
1589	General specimen container IVD, non-sterile, 100 ml, without lid – 1,000 pcs	47775	W0580	03877002407215
1589-50	General specimen container IVD, non-sterile, 100 ml, without lid – 20 × 50 pcs	47775	W0580	03877002407284
1588	Lid for 100 ml specimen container – 1,000 pcs	47775	W0580	03877002407222
1355	General specimen container IVD, no additive, non-sterile 125 ml	47775	W0580	03877000524105
1355-BP	General specimen container IVD, non-sterile, 125 ml, without lid – 1,000 pcs	47775	W0580	03877002407147
1541	Lid for 125 ml specimen container – 1,000 pcs	47775	W0580	03877002407161
1541-50	Lid for 125 ml specimen container – 20 × 50 pcs	47775	W0580	03877002407154
1549	General specimen container IVD, non-sterile, 125 ml, with lid – 5 × 100 pcs	47775	W0580	03877002407178

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1745	General specimen container IVD, no additive, non-sterile,60 ml	47775	W0580	03877000524464
1745-ST	General specimen container IVD, no additive, non-sterile,60 ml with integrated spoon	47775	W0580	03877000524471
1745-P	General specimen container IVD, non-sterile, 60 ml	47775	W0580	03877002407185

Version history

Version	Compiled by	Date	Description
1.0	Sanda Pervan	01/08/2019	First issue.
2.0	Martina Perić	17/08/2020	Formatting changes.
3.0	Martina Perić	21/5/2021	Updating regulatory information.
4.0	Sanda Kolobara	21/6/2023	Updating regulatory information, appendix III/ IV and V.
5.0	Ana Kulaš	06.3.2024.	Updating intended use, intended users and appendix I.
6.0	Dražen Đondraš	28.05.2024	CH-REP address change.
7.0	Ana Kulaš	04.07.2024.	Updating regulatory information.
8.0	Ana Kulaš	23.07.2024.	Added new standard
9.0	Dražen Đondraš	27.2.2026	Updated stanadards
10.	Sanda Kolobara	11.9.2026.	Apendix II

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