

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.

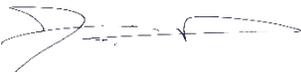
The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

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 non-sterile safe collection and transport of samples of human, animal or non-organic origin
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 Category:	Class A [Rule 5]
Notified Body:	N/A
CE Certificate Reference:	N/A
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 Engineering AG, Rütihof 1, 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.

Name Ivica Vrljičak

Position Managing Director

Signed



Date 16/04/2025

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.

Appendix I -Applicable Standards

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

Standard/Document Name	Description
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
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 (ISO 14971:2019)
EN ISO 6717:2021	In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood
MDCG 2020-16 rev.2	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)
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

Appendix II – Product Listing/Schedule

Part/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
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
1355	General specimen container IVD, no additive, non-sterile 125 ml	47775	W0580	03877000524105
1745	General specimen container IVD, no	47775	W0580	03877000524464

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

Appendix III – Product Listing/Schedule for article 1340

Part/Catalogue Number	Description/Name
L-09184	Urine container with green screw-on lid
L-09184-100	Urine container with green screw-on lid
L-09184-D	Screw-on lid for urine container
L-09184-OD	Urine container with screw threa
L-09184-OD/50	Urine container with screw threa
L-09184-D/50	Screw-on lid for urine container
L-09184-50	Urine container with green screw-on lid

Appendix IV – Product Listing/Schedule for article 1546

Part/Catalogue Number	Description/Name
L-09184-R	Urine container with red screw-on lid

Appendix V – Product Listing/Schedule for article 1355

Part/Catalogue Number	Description/Name
L-09182	Urine container with red snap on lid
L-09182-OD	Urine container without screw thread
L-09182-100	Urine container with red snap on lid
L-09182-D	Snap on lid for urine containers

Appendix V – Product Listing/Schedule for article 1745-ST

Part/Catalogue Number	Description/Name
09188	Stool collector with integrated sampling spoon and red screw-on lid

Version history

Version	Compiled by	Date	Description
1.0	Ana Kulaš	16.04.2025.	First issue.