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 declares that the products named in this document meet the EU Regulation provisionsthat apply to them and the CE Mark may be affixed.

General Product Name:	Sample Container
Basic UDI-DI:	3877000524MC47775XE
Manufacturer:	MA-COM doo, Gospodarsko-poslovna zona Hodovo bb 88360 Stolac, BiH
Variants:	If any. As per Appendix II – Product Listing/Schedule
Intended Use:	Containers for non-sterile, safe collection and transport of samples
Intended User:	Professional use, Home use
IVD Regulation Category:	Class A
Notified Body:	N/A
CE Certificate Reference:	N/A
IVD Directive Assessment Route:	Conformity with the procedure referred to in Annex II and III and drawing up theDeclaration of Conformity in compliance with Annex IV.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name ANA PERIĆ **Position** Managing Director

Signed **Date** 21/5/2020

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 his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

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

Standard/Document Name	Description
(EU) 2017/746	In Vitro Diagnostic Medical Devices Regulation
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	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	GMDN Code
1340	General specimen container IVD, no additive, non-sterile, 100 ml	**47775**
1355	General specimen container IVD, no additive, non-sterile, 125 ml	**47775**
1745	General specimen container IVD, no additive, non-sterile, 60 ml	**47775**
1745-ST	General specimen container IVD, no additive, non-sterile, integrated spoon, 60 ml	**47775**

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.