Date: 21/05/2021

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 provisions that 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	Class A	
Category:		
Notified Body:	N/A	
CE Certificate Reference:	te Reference: N/A	
IVD Directive	tive Conformity with the procedure referred to in Annex II and III and drawing	
Assessment Route:	up the Declaration of Conformity in compliance with Annex IV.	
EU Authorised	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar BKR	
Representative:	4013 Malta	

Name ANA PERIĆ Position Managing Director

ned fin fin 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.

Date: 21/05/2021

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.

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