Declaration of Conformity

for the Medicine cup 30ml

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned 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:	Medicine cup 30ml
Legal Manufacturer: (Name on Label)	**MA-COM doo** Gospodarsko-poslovna zona Hodovo bb 88360 Stolac Bosnia and Herzegovina
SRN:	BA-MF-000009145
Basic UDI-DI:	3877000524MC2091SA
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The purpose of the medicine cup 30 ml is measuring and dispensing of medicine, fluids or tablets.
MDR Classification:	Class Im [Rule 2]
Notified Body:	DNV Product Assurance AS Veritasveien 1 1363 Høvik Norway NB number: 2460
Certificate Number	10000505594-PA-NoMA-BIH
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	In conformity with Annex IX of the Medical Device Regulation

Name Ivica Vrljičak **Position** MANAGING DIRECTOR

Signed _____ **Date** 23/03/2023 **Place** STOLAC, BOSNIA AND HERZEGOVINA

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.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by present Declaration is in conformity with 2017/745/EU Regulation.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management 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
ISO 10993-1:2018	Biological evaluation of medical devices
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN Code	UDI-DI
2091	Medicine cup 30 ml, transparent	12505	13877000524911
2091-B	Medicine cup 30ml, blue	12505	13877000524928
2091-R	Medicine cup 30 ml, red	12505	13877000524935
2091-Y	Medicine cup 30 ml, yellow	12505	13877000524942
2091-G	Medicine cup 30 ml, green	12505	13877000524959

Version History

Version	Compiled by	Date	Description
1.0	Martina Perić	1.12.2021.	First Issue
2.0	Martina Perić	14.1.2022.	Appendix II edit
2.1	Martina Perić	10.3.2022	Page 1 NoBo Certificate Page 2 statement edit.
2.2.	Sanda Kolobara	23.03.2023.	Certifikate number; UDI-DI