



EU DECLARATION OF CONFORMITY

Doc ref :

DoC54250394 OL03 JZ

Date:

05/2021

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Manufacturer:	OneLife S.A. Avenue Albert Einstein, 15 B-1348 Louvain-la-Neuve (Belgium)
SRN Manufacturer:	BE-MF-000003821
Product Name:	Medizyme Foam
Basic UDI-DI	54250394 OL03 JZ
Cat number(s):	OL903xx (see attachment 1)
Intended purpose:	Multi-enzymatic foam spray for surgical instruments and rigid or flexible endoscopes.
Product Category:	GMDN 63385 - Medical device cleaning agent
Product Classification:	Class I
Classification Rule:	Rule 1
Common Specifications used:	Not Applicable
Conformity Assessment Route:	MDR art. 19 + Annex II and III
Notified Body Name and Identification Number:	Not applicable
Certification Type:	Not applicable
Certificate No.:	Not applicable

We herewith declare under our sole responsibility that the above-mentioned medical device(s) to which this declaration relates, are in conformity with the European Medical Device Regulation (2017/745).

Place of Issue

Louvain La Neuve – Belgium

Date of Issue

20 May 2021

Approved By**Name**

Martine Weickmans

Title

R&D manager

Signature

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Attachment 1 List of CE Marked Devices

This Declaration of Conformity applies to the following product codes:

Date of CE marking update for the following catalogue numbers: 26/05/2021

Catalogue No.	Description	UDI-DI
OL90304MDM	Medizyme Foam 750ml ready to use foaming spray	5425039491554