



# EU DECLARATION OF CONFORMITY

Doc ref :

DoC 54250394 OL05 K5

Date:

05/2021

Pag. 1/2

|  |  |
|--|--|
| <b>Manufacturer:</b>                                 | OneLife S.A.<br>Avenue Albert Einstein, 15<br>B-1348 Louvain-la-Neuve (Belgium)  |
| <b>SRN Manufacturer:</b>                             | BE-MF-000003821  |
| <b>Product Name:</b>                                 | Medizyme 3 PLUS  |
| <b>Basic UDI-DI</b>                                  | 54250394 OL05 K5   |
| <b>Cat number(s):</b>                                | OL905xx (see attachment 1)   |
| <b>Intended purpose:</b>                             | Low-foaming liquid enzymatic detergent for cleaning of reusable Medical Devices. |
| <b>Product Category:</b>                             | GMDN 63385 - Medical device cleaning agent                                       |
| <b>Product Classification:</b>                       | Class I  |
| <b>Classification Rule:</b>                          | Rule 1   |
| <b>Common Specifications used:</b>                   | Not Applicable   |
| <b>Conformity Assessment Route:</b>                  | MDR art. 19 + Annex II and III   |
| <b>Notified Body Name and Identification Number:</b> | Not applicable   |
| <b>Certification Type:</b>                           | Not applicable   |
| <b>Certificate No.:</b>                              | 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**

OneLIFE s.a.  
Avenue Albert Einstein, 15  
B-1348 Louvain-la-Neuve  
Belgium

|  |                                     |                      |       |          |
|--|-------------------------------------|----------------------|-------|----------|
|  | <b>EU DECLARATION OF CONFORMITY</b> |                      |       |          |
|  | Doc ref :                           | DoC 54250394 OL05 K5 | Date: | 05/2021  |
|  |                                     |                      |       | Pag. 2/2 |

# EU DECLARATION OF CONFORMITY

## 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        |
|---------------|-------------------|---------------|
| OL90506MDM    | Medizym 3 Plus 5L | 5425039491523 |
| OL90508MDM    | Medizym 3 Plus 1L | 5425039491530 |
|               |                   |               |
|               |                   |               |
|               |                   |               |
|               |                   |               |
|               |                   |               |
|               |                   |               |