BioMylz Private Limited

EC Declaration of Conformity

Manufacturer:

BioMylz Pvt Ltd
Building No.1, #21-D, 2nd Phase, Peenya Industrial Area, Bengaluru-560058, India

whose single Authorized Representative:

Medovis Healthcare GmbH
Marktring 6, 8523 Frauental a.d. L., AUSTRIA
Tel: +43 3462 30 416

Product: ImmunIgY™

Type: IM1

We, the manufacturer, herewith declare that the product covered by the present declaration meets the requirements of REGULATION (EU) MDR 2017/745 of THE EUROPEAN PARLIAMENT and of THE COUNCIL of April 5th, 2017 on MEDICAL DEVICES.

This EC Declaration of Conformity is issued under the sole responsibility of the manufacturer. All supporting documentations are retained under the premises of the manufacturer.

The medical device has been assigned to **Class I**, According to Rule 13, Annex VIII, Regulation (EU) MDR 2017/745 and has been manufactured under a quality management system according to said regulation.

It bears the mark

CE

Compliance of the designated product with the replaced Directive 90/385/EEC, which has been assessed and certified by the Notified Body as per ISO standard, ISO 13485:2016 following the procedure relating to the EC Declaration of Conformity set out for the manufacturing of ImmunIgY.

Bangalore, 27.11.2021
Place Date

Dr. Vasanth Samaga, Director 27/11/2021
Legally binding signature, Function

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