

DECLARATION N°:

2021-01-25

EC DECLARATION OF CONFORMITY N° 2021-01-25

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Class 1 Medical Devices

We

INNOMED, Inc. 103 Estus Drive Savannah, GA 31404, U.S.A.

having designated:

MediMark Europe Sarl., 11 rue Emile Zola – BP 2332. 38033 Grenoble Cedex 2, France

As our European Authorized Representative

having our Quality Management System been certified against ISO 13485:2016 standard (Certificate N° 018365 by SRI Quality System Registrar)

insure and declare under our sole responsibility that the class 1 medical devices specified in the attached list to which this declaration relates are in conformity with the requirements of the Medical Devices Directive 93/42 EEC.

This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC as amended by Directive 2007/47/EC and is valid for an undetermined period of time.

Savannah, GA, 25 January 2021

Name of the authorized person:

Title: Senior VP of Sales

Signature: Missy Squires

Signed by:

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Signer Name: Aaron Ingram

Signing Reason: I approve this document Signing Time: 4/9/2025 | 2:43:20 PM EDT -1417428D09B847D0ACD4D99093A9C519

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List of Class 1 Medical Devices in relation with the above declaration

Device designation / Ref N°	Classification Rule N°
Please see attached 39-page List "2021-01-25 DECLARATION N° 2021- 01-25 " of INNOMED CLASS 1 DEVICES - DoC co-signed MME	Rule 6 Annex IX

Savannah, GA, 25 January 2021

Name of the authorized person:

Title: Senior VP of Sales

Signature: Missy Squires

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Signer Name: Aaron Ingram Signing Reason: I approve this document Signing Time: 4/9/2025 | 2:43:37 PM EDT

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