

Declaration of Conformity for MiniMed Reservoir, Models MMT-326A, MMT-326AT, MMT-332A, MMT- 332AT, MMT-342 & MMT-342T

D00503565

Revision B

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EC Declaration of Conformity

Declaration of Conformity ID: **D00503565**

Manufacturer: Medtronic MiniMed
18000 Devonshire
Street
Northridge CA,
91325 USA

EC Representative: Medtronic BV
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Conformity Assessment Procedure: MDD 93/42/EEC Medical Devices
Directive Annex II, excluding section 4

EC Quality System Certificate: Certificate Number: 8857
Original Expiry: May 26th, 2024
Extended Expiry per Regulation (EU) 2023/607:
December 31, 2028

We, Medtronic MiniMed, declare that the Medical Device(s) specified below comply with Article 120 of the Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607. This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of 93/42/EEC (MDD) or 90/385/EEC (AIMD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607

The validity of the certificates listed on this DoC are valid through 31 December 2028

Notified Body: GMED 0459
1 Rue Gaston
Boissier 75015
Paris
France

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Device name and model numbers: **Medtronic Minimed Reservoirs**
MiniMed Reservoirs, 1.8ml (MMT-326A, MMT-326AT) MiniMed Reservoirs, 3.0 ml (MMT-332A, MMT-332AT) MiniMed Reservoirs, 3.0 ml (MMT-342, MMT-342T)

Conformity with the applicable standard(s) or other normative document(s): Refer to **ERM 9181040DOC** and Tech File BOD **10833499DOC**

Classification: Class IIa (Rule 11, Annex IX)

GMDN Code: **35983**

Other Union Legislations

Union Legislation	Declaration of Conformity Document ID
Restriction of Hazardous Substances Directive[2011/65/EU]	Not Applicable
Radio Equipment Directive [Directive 2014/53/EU]	Not Applicable

Statement:

I, the undersigned, hereby declare on behalf of Medtronic MiniMed and under its sole responsibility, that the Medical Device(s) specified above and provided with CE marking, conform with the Essential Requirements of the EC Directive 93/42/EEC Medical Device Directive. All supporting documentation is retained under the premises of the manufacturer.

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332AT, MMT-342 & MMT-342T**

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Place: Northridge, CA
Name: Mayra Rios Ortiz
Title: Senior Regulatory Affairs Manager

Signature:

DocuSigned by:
Mayra Rios Ortiz
Signer Name: Mayra Rios Ortiz
Signing Reason: I approve this document
Signing Time: 28 March 2024 | 11:46 PDT
EAA3DF32BA58411CA7F51401962B39BB

Date: *Refer to Docusign*