



EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	Manufacturer Address	MHRA Account Number
Defibtech, LLC	741 Boston Post Road Gulfport, CT 06437 United States	0000017259
UKRP/Northern Ireland Authorised Representative Name (if applicable)	UKRP/NI Authorised Representative Address	MHRA Account Number
UKRP: Nihon Kohden UK Ltd.	Unit 3, Heyworth Business Park Old Portsmouth Road, Peasmarsh Guildford, Surrey GU3 1AF United Kingdom	0000011982

I/we declare that:

- the CE certificate(s) listed below were issued under the EU Medical Devices Directive (93/42/EEC) or under the EU Active Implantable Medical Devices Directive (90/385/EEC) on or after 25 May 2017 and were still valid on 26 May 2021 **AND**
- the conditions for extension of the validity of the CE certificate(s) (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificates as listed in the table below

[Complete the relevant table below]

	CE Certificate number/s	Notified Body that issued the CE certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
a) That, in the case of a certificate that expired before 20 March 2023 I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate	N/A	N/A	N/A	N/A	N/A	N/A

	CE Certificate number/s	Notified Body that issued CE certificate	Expiry date/s	Derogation Reference Number & issuing Competent Authority (if any)	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
b) That, in the case of a certificate that expired before 20 March 2023, no such contract (set out in (a) above) was signed before the date of certificate expiry, and the Manufacturer was granted in respect of the device: <ul style="list-style-type: none"> - a derogation from the conformity assessment procedures under EU MDR Article 59 OR - a period of time to carry out conformity assessment in accordance with EU MDR Article 97 	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	CE Certificate numbers	Notified Body that issued the certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
c) The CE certificate(s) was due to expire on or after 20 March 2023, and remains valid by virtue of EU MDR Article 120(2).	HD 2218527-1	TÜV Rheinland 0197	2024-05-26	TÜV Rheinland 0197	2028-12-31	2028-12-31

Signed by Manufacturer:

Robert Jamieson

Robert Jamieson Vice President
QA/RA Debittech LLC April 18, 2024

Name of Signatory

Position of Signatory

Date

Signed by UK Responsible Person/Northern Ireland Authorised Representative (if applicable):

John Hanson

John Hanson

Country Manager UK

May 1st 2024.

Name of Signatory

Position of Signatory

Date

DECLARATION OF CONFORMITY

Manufacturer: **Defibtech LLC**
741 Boston Post Road, Suite 201
Gulford, CT 06437

Declares that the CE marked product:

Product: **Semi-Automatic External Defibrillator**
Models: **DDU-100A, DDU-100B, DDU-100C, DDU-100E, & DDU-100H**

Product: **Battery Pack**
Models: **DBP-1400, DBP-2800, & DBP-H2800**

Product: **Defibrillation/Monitoring Pads**
Models: **DDP-100, DDP-200P**

Complies with all applicable provisions of the Council Directive 93/42/EEC (Medical Device Directive). The technical file required by this Directive is maintained at the Manufacturer site listed above.

Rule 9, Section III (Classification), Annex IX (Classification Criteria) of the Council Directive 93/42 EEC Concerning Medical Device was used to classify the products listed above as Class IIb medical devices following EC conformity path from Annex II, excluding Section 4.

Technical File Reference Document TF-00001 lists all standards that apply.

Valid from 05/25/2021 to 05/26/2024

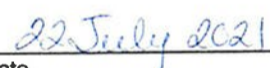
Notified Body: **0197 – TUV Rheinland LGA Products GmbH**
Tillystraße 2, 90431 Nürnberg Germany

Certification Number: **HD 2218527-1**

European Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Nicole Bush
Vice President, Regulatory Affairs and Quality
Defibtech, LLC



Date

DAC-710-BR