Medicines & Healthcare products
Regulatory Agency

EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	Manufacturer Address	MHRA Account Number
Apollo Healthcare Technologies Ltd.	**Unit A1 Gildersome Spur Morley Leeds West Yorkshire LS27 7JZ**	**4239**
UKRP/Northern Ireland Authorised Representative Name (if applicable)	**UKRP/NI Authorised Representative Address**	**MHRA Account Number**
N/A	N/A	N/A

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 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) 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).	DD 2285935-1	TÜV Rheinland LGA Products GmbH	2024-05-26	TÜV Rheinland LGA Products GmbH	2028-12-31	2028-06-30

Signed by Manufacturer: 

David Fletcher	**Business Manager**	**10 June 2024**
Name of Signatory	**Position of Signatory**	**Date**

Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

AHT Holdings Ltd.
Unit A1 Gildersome Spur, Morley, Leeds
West Yorkshire
LS27 7JZ
UNITED KINGDOM

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 16, 2024

Notified Body Confirmation Letter
Reference. : PLA_HZ_2024-05-10

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

AHT Holdings Ltd.
Unit A1 Gildersome Spur, Morley, Leeds
West Yorkshire
LS27 7JZ
UNITED KINGDOM
SRN Number (if available): In progress

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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Germany

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90431 Nuremberg

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Jarosław Pyclik
2024.05.16
10:53:15 +02'00'

Jarosław Pyclik
Certification body

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.:	DD 2285935-1
Manufacturer:	AHT HOLDINGS LTD. Holme Street Liversedge West Yorkshire WF15 6JF United Kingdom
Products:	Active pressure care mattresses for prevention and treatment of pressure ulcers

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.:	84950575-40
Effective date:	2021-05-22
Expiry date:	2024-05-26
Issue date:	2021-05-22

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.