

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2285935-1

Organization: AHT HOLDINGS LTD
Holme Street
Liversedge WF15 6JF West Yorkshire
United Kingdom

Scope: Manufacture, assembly, distribution and service of active and non-active pressure care devices, cushions and associated products for health care industry

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84950575-40
Effective date: 2021-05-22
Expiry date: 2024-05-21
Issue date: 2021-05-22



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



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Organization: AHT HOLDINGS LTD
Holme Street
Liversedge WF15 6JF West Yorkshire
United Kingdom

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	AHT HOLDINGS LTD Holme Street Liversedge WF15 6JF West Yorkshire United Kingdom	Manufacture, distribution and service of active and non-active pressure care devices, cushions and associated products for health care industry
/02	APOLLO HEALTHCARE TECHNOLOGIES LTD Holme Street Liversedge WF15 6JF West Yorkshire United Kingdom	Manufacture, assembly, distribution and service of active and non-active pressure care devices, cushions and associated products for health care industry
/03	APOLLO HEALTHCARE TECHNOLOGIES PTY LTD 38 Lancaster Road Wangara 6065 Australia	Distribution and service of active and non-active pressure care devices, cushions and associated products for health care industry

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Organization: AHT HOLDINGS LTD
Holme Street
Liversedge WF15 6JF West Yorkshire
United Kingdom

The scope of certification includes the following additional sites:

/04	APOLLO HEALTHCARE TECHNOLOGIES (HONG KONG) LTD Room 1112, 11/F Tak Shun Industrial Building 154 Wai Yip Street Kwun Tong, Kowloon Hong Kong	Distribution and service of active and non- active pressure care devices, cushions and associated products for health care industry
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EC Certificate



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 the 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



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.