

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1023621-1

Certificate Holder: HAI Components Poland Sp. z o.o.
ul. Północna 5
67-200 Głogów
Poland

Scope: Production of metal made elements and components for non-invasive medical devices.
Assembling and storage of medical devices for patient positioning and transport.

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.: 84984158-10


Effective date: 2025-07-16

Expiry date: 2027-03-18

Issue date: 2025-07-16

Replaces certificate SX 1023621-1 issued 2025-01-30

This certificate can be validated on <https://www.certipedia.com>



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	HAI Components Poland Sp. z o.o. ul. Północna 5 67-200 Głogów Poland	Production of metal made elements and components for non-invasive medical devices for patient positioning and transport.
/03	HAI Components Poland Sp. z o.o. ul. Południowa 2 67-200 Głogów Poland	Assembling and storage of medical devices for patient positioning and transport.
/04	ASP GmbH Zum Kalkofen 24 57439 Attendorn Germany	Customer support.

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