

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1783036-1

Organization: Happersberger otopront GmbH
Langgasse 90
65329 Hohenstein
Germany


Scope: Design and development, production, distribution and service of medical devices for otorhinolaryngology and active medical devices for endoscopy

TÜVRheinland

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.: 1087435-40
Effective date: 2022-01-25
Expiry date: 2025-01-24
Issue date: 2022-01-13




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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Happersberger otopront GmbH Langgasse 90 65329 Hohenstein Germany	Design and development, production, distribution and service of medical devices for otorhinolaryngology and active medical devices for endoscopy
/02	c/o Happersberger otopront GmbH An der Altwiese 1 65329 Hohenstein Germany	Training, distribution and warehouse

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