CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 104291 0006 Rev. 00

Manufacturer:

AHA Hyperbarics GmbH
Mellergasse 4
1230 Wien
AUSTRIA

SRN Manufacturer - AT-MF-000023416

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 104291 0006 Rev. 00

Report No.: 713310235
Valid from: 2026-07-23
Valid until: 2031-07-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-07-23

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Classification:	Class IIb
Device Group:	Z120308 - HYPERBARIC CHAMBERS
Intended Purpose:	AHA Flex hyperbaric chambers are intended to perform hyperbaric oxygen therapy.
Classification:	Class IIb
Device Group:	Z12159004 - OXYGEN CONCENTRATORS
Intended Purpose:	AHA Oxy oxygen concentrators are intended to perform hyperbaric oxygen therapy (to be used with the hyperbaric chamber).
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2026-07-23	713310235	Initial issuance

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