CERTIFICATE

Certificate No:
TALB000004K Rev.1

Particulars of Manufacturer

Manufacturer:	**GS Elektromedizinische Geräte G. Stemple GmbH**
Address:	**Hauswiesenstr. 26** **86916 Kaufering** **Germany**

Particulars of Product

Type:	**corpuls³ Hyperbaric (HBO)**
Devices:	**Monitoring unit, Patient box, Defibrillator/Pacer unit**
Power Supply:	**12 V DC extern and Li-Ion secondary battery for each device (module)**
Environmental conditions:	Temperatures: **0 – 45°C** Dust and splash-proof: **IP55** Min. working pressure: **0 barg (0 m) in air** Max. working pressure: **3 barg (30 m) in air**

This is to certify:

that the product:	**corpuls³ Hyperbaric (HBO)**
Intended for the following service:	**Defibrillator/monitoring device for the use under hyperbaric conditions up to 3 barg**

Has been built and tested in accordance with the relevant requirements of DNV Rules for Classification of Underwater Technology.

The safe technical performance of the corpuls³ devices under hyperbaric conditions was verified during testing. Under consideration of the below-mentioned remarks we have no objections against the intended use of the patient monitoring system with defibrillator/pacer under hyperbaric conditions up to 3 barg.

Following corpuls³ components were tested under the supervision of DNV experts:

The corpuls³ devices have undergone a type approval cyclic pressure testing with at least 6 barg based on GL Rules for Underwater Technology, Chapter 1 – Diving Systems and Diving Simulators, Section 2, N, 4.5.2 (equivalent to DNV RU UWT Pt.4 Ch.8 Sec.3 [2.1]) and have remained in sound condition.

The Li-Ion second battery has performed charging and discharging procedures under type approval conditions and has been found suitable for use under hyperbaric conditions. The evaluation is based on the safety concept of the corpuls³ battery management system and the UN test reports.

The NIBP module and printer module as well as the connection units have undergone a functional testing under 2 barg in oxygen environment and have remained in sound condition.

Additionally, functional tests of the devices were performed during practical operation in a medical hyperbaric facility.

The initial examination is based on the approval letter with Ref. No. 12-043811.

For extension of the initial Certificate 77545-12 HH dated 2012-05-08 the status of the corpuls³ manufacturing and testing process was subjected to a successful renewal assessment on 2015-04-22, 2018-03-28, 2021-04-14 and 2024-01-25.

Remarks:

- This certificate covers only the delta between the corpuls³ for atmospheric (original status) and hyperbaric conditions.
- We take for granted that a periodic safety inspection guarantees the safe operation of the corpuls³ defibrillator under hyperbaric conditions.
- The personnel accompanying and operating the corpuls³ under hyperbaric conditions has to be familiar with the equipment, be aware of possible risks and trained on safety measures accordingly.
- Any corpuls³ device has to be clearly marked for hyperbaric use and has to perform a routine cyclic pressure testing based on DNV RU UWT Pt.4 Ch.8 Sec.3 [2.2] prior to the final functional test.
- Modification of or additional/changed equipment requires document approval, acceptance and functional tests to be carried out and certified accordingly by DNV GL.

This Certificate is valid until May 2027

The product was marked: **HBO**

Issued at **Hamburg** on **2024-05-27**

for **DNV**

Jonathan Struwe
Head of Section
Underwater Technology