

Certificate ES22/00000053

The quality management system of

# OXYBARICA IMPACTOS INTERNACIONALES, S.L.

Avenida de la Industria, 55 45200 ILLESCAS (Toledo) – SPAIN

Facility Identification Number: F005962

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

## MDSAP (ISO 13485:2016)

### Australia:

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

### United States:

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

For the following activities and devices

Design, manufacturing, installation and service of hyperbaric chambers.

This certificate is valid from Effective Date: 25 May 2022 until Expiry Date: 24 May 2025 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 December 2024

Issue 1. Certified since 25 May 2022

Authorised by



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