

CERTIFICATE

Management System as per ELOT EN ISO 13485 : 2012

In accordance with TÜV AUSTRIA procedures, it is hereby certified that



SC OXYHELP INDUSTRY SRL

Headquarter: Sos. Panduri No. 15, Bucuresti Sector 5, BUCURESTI, ROMANIA

Storage: Tabacarilor 16, Sector 4, 040298 BUCURESTI, ROMANIA

Production and Storage: 10 Sperantei Str., Bragadiru, Jud, Ilfov, BUCURESTI,

ROMANIA

Applies a Quality Management System for Medical Devices in line with the above Standard for the following Scope

DESIGN, DEVELOPMENT, PRODUCTION, DISTRIBUTION, INSTALLATION AND SERVICE OF HYPERBARIC OXYGEN THERAPY DEVICES.

Certificate Registration No.: 01215010

Valid until: 2021-05-04 Initial certification: 2015-05-05

Haralabos Ageloudis

Head of Management Systems & Products Certification Division

Certification Body at TÜV AUSTRIA Athens, 2018-05-05

This certification was conducted in accordance with TÜV AUSTRIA auditing and certification procedures and is subject to regular surveillance audits.

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