

# MANAGEMENT SYSTEM **CERTIFICATE**

Certificate no. 1397GB451230217 Final assessment report no. 1397AU28F

Effective date 2023-02-17

Expiry date

This is to certify that the management system of

## THAYER MEDICAL CORPORATION

4575 S. Palo Verde, Suite 337, Tucson AZ 85714, United States of America

Facility ID: F006016

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

## ISO 13485:2016 and the following country-specific requirements

Australia: Canada:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 Medical Devices Regulations (SOR/98-282) - Part 1 (applicable requirements)

United States:

21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date Hamburg, 2023-02-17

> DNV MEDCERT is an MDSAP authorised auditing organisation

For the issuing office DNV MEDCERT GmbH Pilatus pool 2, 20355 Hamburg, Germany

Markus Bianchi Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de



Certificate no.: 1397GB451230217 Place and date: Hamburg, 2023-02-17

#### Activities and products/services covered by this certificate

Design and development, manufacturing and distribution of

- Breathing circuit adapters
- Metered dose inhaler adapters
- Holding chambers
- Positive expiratory pressure devices

for use in respiratory therapy

#### Sites covered by this certificate

THAYER MEDICAL CORPORATION, 4575 S. Palo Verde, Suite 337, Tucson AZ 85714, United States of America Facility ID: F006016

Site-specific scope

Design and development, manufacturing and distribution of

- Breathing circuit adapters
- Metered dose inhaler adapters
- Holding chambers
- Positive expiratory pressure devices

for use in respiratory therapy