CERTIFICATE

This is to certify that the company

THAYER MEDICAL CORPORATION

4575 South Palo Verde Road, Suite 337
Tucson, AZ, 85714-1961
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certificate and applicable country-specific requirements:
The design and development, manufacturing and distribution of breathing circuit adapters, metered dose inhaler adapters, holding chambers and positive expiratory pressure devices for use in respiratory therapy.
-AUS (a), CND, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no.	287147 MDSAP16
Certificate unique ID	170721412
Effective date	2018-11-20
Expiry date	2021-11-19
Frankfurt am Main	2018-11-20

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

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Managing Director

Szymon Kurdyn
Product Manager

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DQS Medizinprodukte GmbH is authorised under the Medical Devices Single Audit Program.
Visit https://www.mydqs.com/en/customers/customer-database.html to validate this certificate.

413.01.001 Version 1.0

Annex to certificate
Certificate registration No.: 287147 MDSAP16
Certificate unique ID: 170721412
Effective date: 2018-11-20

THAYER MEDICAL CORPORATION

4575 South Palo Verde Road, Suite 337
Tucson, AZ, 85714-1961
United States of America

Audited site	DUNS No., site scope and country-specific requirements
THAYER MEDICAL CORPORATION 4575 South Palo Verde Road, Suite 337 Tucson, AZ, 85714-1961 United States of America	The design and development, manufacturing and distribution of breathing circuit adapters, metered dose inhaler adapters, holding chambers and positive expiratory pressure devices for use in respiratory therapy. **-AUS (a), CND, USA (a,b,c,d)** **DUNS No.: 626238844**

Annex to certificate
Certificate registration No.: 287147 MDSAP16
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821