CERTIFICATE

This is to certify that the company

TNI medical AG

Hofmannstrasse 8
97084 Würzburg
Germany

with the organizational units/sites as listed in the annex

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

Scope of certification:
Design and development, manufacturing, distribution, installation and servicing of high-flow therapy devices and accessories.
- 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

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	390773 MDSAP16
Certificate unique ID	170777465
Effective date	2021-09-08
Expiry date	2022-04-11
Frankfurt am Main	2021-09-08

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 390773 MDSAP16
Certificate unique ID: 170777465
Effective date: 2021-09-08

TNI medical AG

Hofmannstrasse 8
97084 Würzburg
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
390773 **TNI medical AG** Hofmannstrasse 8 97084 Würzburg Germany	Design and development, manufacturing, distribution, installation and servicing of high-flow therapy devices and accessories. **- AUS (a), CND, USA (a, b, c, d)** **REPs FEI No.: F005444**

Annex to certificate
Certificate registration No.: 390773 MDSAP16
Certificate unique ID: 170777465
Effective date: 2021-09-08

TNI medical AG

Hofmannstrasse 8
97084 Würzburg
Germany

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