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Clinical Experience
Technical Competence

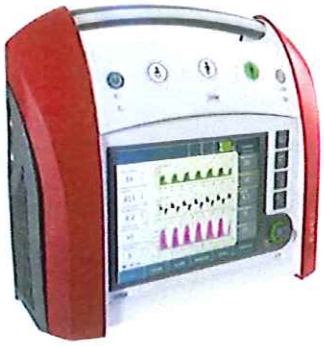
Geschäftsführung
Rainer Hafermann
Bernd Höhne

USt-IdNr.: DE 199109395
Handelsregister Amtsgericht
Montabaur HRB 4241

Certificate

EVE_{TR}

Transport-Respirator



Full Quality Management System Certificate:

The medical device has been developed, manufactured and tested according to the applicable Full Quality Assurance Procedures.

Certificate	Cert. No	Issued By	Issue Date
EN ISO 13485:2012 + AC:2012	0930GB43810731	MEDCERT GmbH Pilatuspool 2 20355 Hamburg / Germany	31.07.2018
EC Certificate of Conformity Annex II excluding section 4	0930GB410150703	MEDCERT GmbH Pilatuspool 2 20355 Hamburg / Germany	03.07.2015
ISO 9001:2008	164013-2014-AQ-GER-DAkkS	DNV GL - Business Assurance Schnieringshof 14, 45329 Essen, Germany	23.08.2017

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Applied Standards:

The mechanical stability and electromagnetic compatibility in the context of transport in helicopters, fixed wing aircrafts and ambulances of EVE_{TR} is in full compliance with the following standards / clauses:

Standard	Section	Description
IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012 Medical electrical equipment	All clauses	Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007 + Cor.:2010 Medical electrical equipment	All clauses	Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and test
IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment	All clauses	Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability
IEC 60601-1-8:2006 + A1:2012 Medical electrical equipment	All clauses	Part 1-8: General requirements for safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304:2006 + A1:2015 Medical device software	All clauses	Software life-cycle processes
IEC 62366:2007 Medical devices	All clauses	Application of usability engineering to medical devices
IEC 80601-2-12:2011 + Cor.:2011 Medical electrical equipment	All clauses	Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-55:2011 Medical electrical equipment	All clauses	Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-61:2011 Medical electrical equipment	All clauses	Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 794-3:1998 + A2:2009 Lung ventilators	All clauses* *10.2.1 a with O2-sensor switched off	Part 3: Particular requirements for emergency and transport ventilators
ISO 10651-3:1997 Lung ventilators for medical use	All clauses* *Except 5.8	Part 3: Particular requirements for emergency and transport ventilators

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Standard	Section	Description
DIN EN 1789:2007 + A1:2010 Medical vehicles and their equipment	Section 6.3.2	Temperature
	Section 6.3.5	Fixation of devices
	Section 6.4	Mechanical Strength – Test methods for medical devices for use in road ambulances
RTCA DO 160G:2010 Environmental conditions and test procedures for airborne equipment	Section 7.2.1	Operational shock category E
	Section 7.3.1	Crash safety category E
	Section 8.5.2	Broad brand random (Standard – Fixed Wing Aircraft) Category S
	Section 8.7.2	Broad brand random (Robust – Fixed Wing Aircraft) Category R
	Section 8.8.3	Broad brand random (Helicopter – Unknown Frequencies) Category U2

Gackenbach, 03rd September, 2018

Fritz Stephan GmbH
Kirchstraße 19, 56412 Gackenbach, Germany

Bernd Höhne
CEO