



EC DECLARATION OF CONFORMITY

Company:	Sunrise Medical HCM B.V. Vossenbeemd 104 5705 CL Helmond The Netherlands +31 (0)492 - 59 38 88 E: info@sunrisemedical.nl www.SunriseMedical.eu
Product:	Product group: Manual wheelchair (including accessories) Brand: Exigo, Emineo Cirrus Model: Exigo 20 and 30, Cirrus G5, Emineo
<p>We, Sunrise Medical declare under our sole responsibility that the product(s) to which this declaration relates, is a class 1 device, and is in conformity with the requirements of EC Council Directive for Medical Devices 93/42/EEC.</p> <p>This was verified with conformity evaluation procedures according to Medical Device Directive Annex VII.</p>	

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Form Owner: Heads of Engineering	Form Approver: Global Head of Engineering	GMS Change Number:

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The following standards or other normative documents are used;

EN ISO 12183, Manual wheelchairs - Requirements and test methods with includes the following elements:

ISO 7176-1 Determination of static stability

ISO 7176-3 Determination of effectiveness of brakes

ISO 7176-8 Requirements and test methods for static, impact and fatigue strengths

ISO 7176-15 Requirements for information disclosure, documentation and labelling

ISO 12182, Assistive products for persons with disability - General requirements and test methods

•4.2 Intended performance and technical documentation

•4.3 Clinical evaluation

•4.4 Aids that can be dismantled

•4.5 Single use fasteners

•5.3 Biocompatibility and toxicity

•5.4 Contaminants and residues (assess only oils, grease and batteries)

•5.5 Infection and microbiological contamination

•9 Overflow, spillage, leakage, and ingress of liquids

•12 Safety of moving parts

•13 Prevention of traps for parts of the human body

•14 Folding and adjusting mechanisms

•18 Surfaces, corners and edges

•23 Ergonomics

EN ISO 1021-2 Assessment of the ignitability of upholstered furniture

ISO 10993-5 Biocompatibility and toxicity (5.3 EN 12182)

ISO 7176-19 Wheeled mobility devices for use as seats in motor vehicles

EN ISO 14971 Medical devices - Application of risk management to medical devices

Tom Myklebust, Marketing Director	2	05-November-15
Approval Name and Function	Revision	Approval Date


Signature (Sunrise Medical Approval representative)

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