



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: (May include accessories)	Product group: Rollator (including accessories) Brand: Gemino Model: 20, 20 M, 20S, 30, 30 M, 30 S, 30 Walker, 30 M Walker, Gemino 60, Gemino 60 M, Gemino 60 Walker, Gemino 60 M Walker, Gemino 30 Speedcontrol, Gemino 30 Parkinson, Gemino 30 M Parkinson
--	---


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.
This was verified with conformity evaluation procedures according to Medical Device Directive Annex VII.

GMS Form Number:	Revision: B	Effective Date: 01.02.2010
Form Owner: Heads of Engineering	Form Approver: Global Head of Engineering	GMS Change Number:
Page 1 of 2		

The following standards or other normative documents are used;

EN ISO 11199-2 Walking aids manipulated by both arms – Requirements and test methods – Part 2: Rollators (ISO 11199-2:2005)
EN ISO 11199-3 Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables (ISO 11199-3:2005)
EN ISO 14971:2009 Medical devices - Application of risk management to medical devices - (ISO 14971 :2007, Corrected version 2007-10-01)
EN 12182 Assistive products for persons with disability - General requirements and test methods – (EN 12182:2012)
EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)
EN ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

Tom Myklebust, Marketing Director	3	13-April-16
Approval Name and Function	Revision	Approval Date


Signature (Sunrise Medical Approval representative)

GMS Form Number:	Revision: B	Effective Date: 01.02.2010
Form Owner: Heads of Engineering	Form Approver: Global Head of Engineering	GMS Change Number:
Page 2 of 2		