



## EC DECLARATION OF CONFORMITY

<b>Company:</b>	Sunrise Medical HCM B.V. Vossenbeemd 104 5705 CL Helmond The Netherlands +31 (0)492 - 59 38 88 E: <a href="mailto:info@sunrisemedical.nl">info@sunrisemedical.nl</a> <a href="http://www.SunriseMedical.eu">www.SunriseMedical.eu</a>
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<b>Product:</b> (May include accessories)	<b>Product group:</b> Rollator (including accessories) <b>Brand:</b> Gemino <b>Model:</b> 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
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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>B</b>	Effective Date: <b>01.02.2010</b>
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 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
<b>Approval Name and Function</b>	<b>Revision</b>	<b>Approval Date</b>

  
**Signature** (Sunrise Medical Approval representative)

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