

**Declarati**

Model 8637, SynchroMed II Programmable Pump

Version	Description
2.0	This version contains updated standards versions and certificate numbers. This EC DoC contains information for the AIMD and R&TTE Directives.

**1. GENERAL DEVICE INFORMATION**

GENERAL DEVICE INFORMATION	
<b>Manufacturer:</b>	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
<b>Description of device concerned:</b>	SynchroMed II Programmable Pump
<b>Model number:</b>	8637
<b>Variants:</b>	8637-20, 8637-40

**2. EC DECLARATION OF CONFORMITY**

SPECIFIC EC DECLARATION OF CONFORMITY INFORMATION	
<b>EC Representative:</b>	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
<b>GMDN Code:</b>	35687
<b>GMDN Term:</b>	Infusion pump, implantable, programmable
<b>Classification, rule:</b>	AIMD
<b>Conformity Assessment Route:</b>	Annex 2.3 with Annex 2.4
<b>EC Certificate:</b>	17 10 05 39709 658
<b>EC Quality System Certificate:</b>	11 10 05 39709 652
<b>Name of Notified Body:</b>	TÜV SÜD PS GmbH, Ridlerstrasse 65, D-80339 München, Germany
<b>Notified Body Identification Number:</b>	0123
<b>Statement:</b> I, the undersigned, hereby declare that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC, including amendments issued in the years following, which apply to them. This declaration is supported by the above Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.	



