

Declaration of Conformity

Application of Council Directive 93/42/EEC



Self-Certified

Manufacturer:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 USA	Phone: 269-323-7700 800-253-3210 Fax: 269-324-5412
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European Representative: Stryker European Operations B.V.
Herikerbergweg 110
Amsterdam
1101 CM
Netherlands

Product Group: Large Bone Powered Surgical Systems
Product Class and Rule: Class I, Rule 1, Non-Sterile
Product Number: See Attached List
Conformity Assessment Route: Annex VII, EC Declaration of Conformity

According to Annex VII of the Council Directive 93/42/EEC concerning Medical Devices, we declare under our sole responsibility that the distributed CE marked products as specified above, meet the provisions of the Council Directive 93/42/EEC concerning medical devices, which apply to them.

The above product complies with Council Directive 93/42/EEC, Annex I (Essential Requirements) and has been subject to conformity assessment in accordance with the route identified above. This declaration of conformity is valid when coupled with the certificate of compliance of each lot produced.

I, the undersigned, declare on the basis of the above information that the system described above is in compliance with the applicable requirements of Directive 93/42/EEC.

This declaration hereby authorizes the CE Mark to be affixed to the above mentioned product.

Reviewed and Approved By: David Colao **Date:** 5 Sep 2017
 David Colao, Sr. Regulatory Affairs
 Manager

Declaration of Conformity Number: DOC-072
Revision Level: F

Attachment to DOC

Product Number	Product Name	Date of CE Mark (Day-Month-Year)
6110-426-000	Non-Sterile Battery Charger Module	13-Sep-2006
6110-625-000	System 6 Module	13-Sep-2006
6126-000-000	System 6 Aseptic Battery Kit	19-Dec-2006
6126-110-000	System 6 Non-Sterile Battery	19-Dec-2006
6126-120-000	System 6 Aseptic Housing	04-Jan-2007
6126-130-000	System 6 Transfer Shield	19-Dec-2006
6127-000-000	System 6 Small Aseptic Battery Kit	11-Feb-2006
6127-120-000	System 6 Small Aseptic Housing	11-Feb-2006
6212-000-000	Battery	06-Sept-2006
6215-000-000	Battery	11-Aug-2006
7110-120-000	Universal Battery Charger	23-Aug-2012
7126-110-000	Stryker SmartLife™ Large Non-sterile Battery	27-Mar-2013
7126-120-000	Stryker SmartLife™ Large Aseptic Housing	27-Mar-2013
7126-130-000	Stryker SmartLife™ Large Transfer Shield	27-Mar-2013
7212-000-000	Stryker SmartLife™ Battery Pack, Small	23-Aug-2012
7215-000-000	Stryker SmartLife™ Battery Pack, Large	23-Aug-2012
7222-110-000	Stryker SmartLife™ Small Non-Sterile Battery	27-Mar-2013
7222-120-000	Stryker SmartLife™ Small Aseptic Housing	27-Mar-2013
7222-130-000	Stryker SmartLife™ Small Transfer Shield	27-Mar-2013
4110-420-000	System 4 Charger Software Upgrade Kit Version 1.1	21-Jun-2002
4222-110-000	Non-Sterile Small Battery	29-Oct-2002
4222-130-000	Small Transfer Shield	29-Oct-2002