

# Declaration of Conformity

Application of Council Directive 93/42/EEC



Self-Certified

<b>Manufacturer:</b>	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

<b>Product Group:</b>	Large and Small Bone Powered Surgical Systems
<b>Product Class and Rule:</b>	Class I, Rule 1, Non-Sterile
<b>Product Number:</b>	See Attached List
<b>Conformity Assessment Route:</b>	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:** 9 Nov 2017  
David Colao, Sr. Regulatory Affairs  
Manager

Effective Date: 12 June 2017

**Declaration of Conformity Number:** DOC-089  
**Revision Level:** J

**Attachment to DOC**

Product Number	Product Name	Date of CE Mark (Day-Month-Year)
7102-450-040	3/4 Size x 8 inch (200 mm) Case	05-Apr-2013
7102-453-010	System 7 Sternum/SABO® Insert Tray	05-Apr-2013
7102-453-040	1/2 Size x 6 inch (150 mm) Case	05-Apr-2013
7102-454-010	System 7 3 Handpiece Insert Tray	05-Apr-2013
7102-454-040	3/4 Size x 6 inch (150 mm) Case	05-Apr-2013
7102-452-010	System 7 2 Handpiece Insert Tray	05-Apr-2013
7102-452-040	1/2 Size x 8 inch (200 mm) Case	05-Apr-2013
7102-458-010	System 7 Aseptic Handpiece Insert Tray	05-Apr-2013
7102-455-010	System 7 Aseptic Housing Insert Tray	05-Apr-2013
7102-455-040	Full Size x 6 inch (150 mm) Case	05-Apr-2013
4405-452-010	Cordless Driver 4/Sabo2™ Insert Tray	05-Apr-2013
4405-453-010	Cordless Driver 4/Sabo2™ 1 Hp Insert Tray	10-Nov-2015
7102-459-010	EZout™ Insert Tray	27-Apr-2016
4405-451-010	Trauma Insert Tray	12-Sept-2016
6400-277-010	Small Bone Insert Tray	12-Sept-2016
1900-375-010	Hybrid Insert Tray	17-Apr-2017
4300-452-000	Sports Medicine/Small Bone Trauma Sterilization Case	23-May-2008
4300-465-000	Cordless Driver 3 Sterilization Case	12-Dec-2007
4200-465-000	Cordless Driver Sterilization Case, Large	17-Apr-2002
4222-450-000	Cordless Driver Aseptic Battery Kit Sterilization Case, Small	29-Oct-2002
6102-453-000	System 6 Sternum Saw Sterilization Case	13-Sep-2006
6102-455-000	System 6 Aseptic Battery Kit Sterilization Case	17-Sep-2009
6102-450-000	System 6 Sterilization Case, Large	11-Aug-2006
6102-452-000	System 6 Mini Sterilization Case	07-Jun-2006
6102-454-000	System 6 Sterilization Case	12-Sep-2006
6102-456-000	System 6 Aseptic Battery Kit Sterilization Case, Small	03-Jan-2008