

DECLARATION OF CONFORMITY



Form No : ZPC 1.2100/G

Revision : 07

Declaration
Number : 086

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Legal Manufacturer:

Zimmer Surgical, Inc.
200 West Ohio Avenue
Dover, Ohio, USA 44622

EC Representative:

Biomet GSCC BV
Hazeldonk 6530
4836 LD Breda
The Netherlands

Notified Body Information:

BSi Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Identification Number:



Conformity Assessment Route:


Annex II excluding section 4

I, undersigned, hereby declare that the products listed below meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking by Notified Body **BSI**, Identification Number **2797**. This declaration is also supported by the EC Quality System approval to ISO 13485 issued by **BSI**.

References:

CE-Certificate Number: CE 517465

Tech File Number: 086

 07 Dec 2020
Signature and date

Jennifer Everett, Regulatory Affairs Associate Director
Name and Title

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Part Number	Description	First Lot Number/Date of CE Marked Product	Device Classification (Applicable Rules)
60-4000-101-00	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor	10/2013	IIb (9)
60-4000-301-01	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – ZH SIMP	10/2013	IIb (9)
60-4000-301-02	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – ZH TRAD	10/2013	IIb (9)
60-4000-301-03	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – DA	10/2013	IIb (9)
60-4000-301-04	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – NL	10/2013	IIb (9)
60-4000-301-05	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – FI	10/2013	IIb (9)
60-4000-301-06	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – FR	10/2013	IIb (9)
60-4000-301-07	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – DE	10/2013	IIb (9)
60-4000-301-08	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – IT	10/2013	IIb (9)
60-4000-301-09	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – JA	10/2013	IIb (9)
60-4000-301-10	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – KO	10/2013	IIb (9)
60-4000-301-11	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – PT	10/2013	IIb (9)
60-4000-301-12	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – ES	10/2013	IIb (9)
60-4000-301-13	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – SV	10/2013	IIb (9)
60-4000-301-14	A.T.S. 4000TS Tourniquet w/ Hoses and LOP Sensor – BR	10/2013	IIb (9)

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Revision No.	Revision Description	Change Notice No.
00	Initial Release	CN 21203
01	Update BSI address in the notified body information section	CN 21855
02	Add appropriate year references to Applicable Standards section	CN 22471
03	Update the conformity assessment route to list the exclusion	CN 22732
04	Updated risk standard to latest version and updated electrical safety standards to reflect current test reports for compliance to fourth edition.	CN 22775
05	<p>Periodic review of tech file 086. Referenced external standards were updated:</p> <ul style="list-style-type: none">- ISO 13485 updated to 2016 version- MED DEV 2.7/1 revision 4 title updated- EN 980 removed- EN 62304:2006 added- BSI EN 62366:2008 + A1:2015 added- Biocompatibility standards updated- Harmonized and non-harmonized standards for 60601 were merged into the same cell- Added harmonized version of ISO 10993-1:2009 to include EN ISO 10993-1:2009 and <p>Removed ISO 14664-1 and 14664-5 as there are no sterile SKUs in the tech file. Removed ANSI/AAMI/ISO 10993-17 and AAMI 10993-4:2002 from standards list as the standard are not applicable to the intended use of the ATS devices.</p>	CN 23227
06	<ul style="list-style-type: none">• Updated to new template which removed reference to Applied Standards.	CN 23730
07	<ul style="list-style-type: none">• Updated Notified Body & Auth Rep information throughout the DoC to reflect changes made for Brexit	CN 24248