DECLARATION OF CONFORMITY

Legal Manufacturer:

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

Notified Body Information:

BSi Product Services
Kitemark Court, Davy Avenue, Knowlhill
Milton Keynes MK 5 8PP United Kingdom

Identification Number: CE 0086

EC Representative:

Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, Wiltshire SN3 4FP
United Kingdom

Conformity Assessment Route:
Annex II

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 0086.** 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: 019

Kolleen Tener 20 Jan 2017
Signature and date

Kolleen Tener, Regulatory Compliance Manager
Name and Title

Digitally signed by Kalcev Ghennadi
Date: 2020.09.15 13:38:29 EEST
Reason: MoldSign Signature
Location: Moldova

Product List:

Part Number	Description	First Lot Number/Date of CE Marked Product	Device Classification (Applicable Rules)
00-8801-001-00	Air Dermatome Handpiece	6/98	IIb (4, 11)
00-8802-001-00	Width Plate 1"	31754600	IIb (4)
00-8802-002-00	Width Plate 2"	31732900	IIb (4)
00-8802-003-00	Width Plate 3"	31733000	IIb (4)
00-8802-004-00	Width Plate 4"	31788900	IIb (4)
00-8802-015-00	Width Plate 1.5"	31825900	IIb (4)
00-8821-001-00	Electric Dermatome Handpiece	31717000	IIb (4, 11)
00-8821-006-00	Electric Dermatome Power Supply	31717200	IIb (11)
00-8851-001-00	Air Dermatome II Handpiece	12/11	IIb (4, 11)
00-8851-001-01	Air Dermatome II Handpiece without Hose	12/11	IIb (4, 11)
00-8851-201-00	Air Dermatome II Width Plate 1"	12/11	IIb (4)
00-8851-202-00	Air Dermatome II Width Plate 2"	12/11	IIb (4)
00-8851-203-00	Air Dermatome II Width Plate 3"	12/11	IIb (4)
00-8851-204-00	Air Dermatome II Width Plate 4"	12/11	IIb (4)
00-8851-215-00	Air Dermatome II Width Plate 1.5"	12/11	IIb (4)
8870N100	Air Dermatome AN Width Plate 1"	**63561632**	IIb (4)
8870N150	Air Dermatome AN Width Plate 1.5"	**63561633**	IIb (4)
8870N200	Air Dermatome AN Width Plate 2"	**63561634**	IIb (4)
8870N300	Air Dermatome AN Width Plate 3"	**63561636**	IIb (4)
8870N400	Air Dermatome AN Width Plate 4"	**63561637**	IIb (4)
88710100	ZIMMER DERMATOME AN	**63565387**	IIb (4, 11)

Applied standards in full or in part:

Standard No:	Title
MDD 93/42/EEC	Medical Device Directive – EU

Standard No:	Title
SOR/98-282	Medical Device Regulations – Canada
21 CFR 820	Medical Device Regulations – FDA
ISO 13485:2003	Medical Devices- Quality Management Systems-Requirements for regulatory purposes
ISO 14971:2009	Medical Devices- Application of Risk Management to Medical Devices
ISO 14644-1:1999	Cleanrooms and associated controlled environments – Part 1
ISO 14644-5:2004	Cleanrooms and associated controlled environments – Part 5
EN 980	Symbols for use in labeling of medical devices
EN 1041	Information supplied by the manufacturer of medical devices
ASTM D4169:2009	Standard Practice for Performance Testing of Shipping Containers and Systems.
RoHS 2011/65/EU	Restriction of Hazardous Substances in electrical and electronic equipment
MED DEV 2.7.1	Clinical Evaluation For Manufacturers and Notified Bodies
IEC 60601-1	Medical Electrical Equipment : Part 1 – General requirements for Basic Safety and Essential Performance
EN 60601-1-2	Medical electrical equipment Part 1-2: General requirements for Safety – Collateral Standard: Electromagnetic compatibility Requirements and tests
ANSI/AAMI/ISO 10993-17	Biological evaluation of medical devices Part 17 – Establishment of allowable limits for leachable substances
ISO 10993-1	Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management process
AAMI 10993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood.

Revision History:

Revision No.	Revision Description	Change Notice No. if applicable
00	Initial Release	CN 21203
01	Update BSI address in the notified body information section	CN 21855
02	Updated to include new dermatome products	CN 22016

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Conformity Assessment Route:
Annex VII

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 0086.** This declaration is also supported by the EC Quality System approval to ISO 13485 issued by **BSI.**

References:

CE-Certificate Number: N/A (Annex VII, Self-Declared)

Tech File Number: 019

Kolleen Tener 20 Jan 2017
Signature and date

Kolleen Tener, Regulatory Compliance Manager
Name and Title

Product List:

Part Number	Description	First Lot Number/Date of CE Marked Product	Device Classification (Applicable Rules)
00-8801-002-00	Dermatome Hose	31823700	I (1)
00-8801-003-00	Dermatome Autoclave Case	31732800	I (1)
00-8803-000-00	Dermatome Screwdriver	31733100	I (1)
00-8851-002-02	Air Dermatome II Hose: Draeger, 3m	12/11	I (1)
00-8851-002-03	Air Dermatome II Hose: Synthes (AO), 3m	12/11	I (1)
00-8851-002-04	Air Dermatome II Hose: Heyer, 3m	12/11	I (1)
00-8851-002-05	Air Dermatome II Hose: AGA, 3m	12/11	I (1)
00-8851-002-06	Air Dermatome II Hose: UK MA-7 Schrader, 3m	12/11	I (1)
00-8851-002-07	Air Dermatome II Hose: DIN, 3m	12/11	I (1)
00-8851-003-00	Air Dermatome II Autoclave Case	12/11	I (1)
00-8851-205-00	Air Dermatome II Screwdriver	12/11	I (1)
88700300	Air Dermatome AN Autoclave Case	63563707	I (1)
88700500	Air Dermatome AN Screwdriver	63561630	I (1)

Applied standards in full or in part:

Standard No:	Title
MDD 93/42/EEC	Medical Device Directive - EU
SOR/98-282	Medical Device Regulations - Canada
21 CFR 820	Medical Device Regulations - FDA
ISO 13485:2003	Medical Devices- Quality Management Systems-Requirements for regulatory purposes
ISO 14971:2009	Medical Devices- Application of Risk Management to Medical Devices
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ISO 14644-5:2004	Cleanrooms and associated controlled environments – Part 5
EN 980	Symbols for use in labeling of medical devices

Standard No:	Title
EN 1041	Information supplied by the manufacturer of medical devices
ASTM D4169:2009	Standard Practice for Performance Testing of Shipping Containers and Systems.
MED DEV 2.7.1	Clinical Evaluation For Manufacturers and Notified Bodies

Revision History:

Revision No.	Revision Description	Change Notice No. if applicable
00	Initial Release	CN 21203
01	Update BSI address in the notified body information section	CN 21855
02	Update to include new dermatome products	CN 22016