

REVISION HISTORY**EC DECLARATION OF CONFORMITY****TECHNICAL FILE NUMBER** | CE-004

REVISION HISTORY DESCRIPTION	REVISION	IMPLEMENTATION DATE
First Issue Product Transfer	New	April 14, 2003
➤ Restructured Declaration of Conformity - Midas Rex Electric High Speed Drill System	1	July 15, 2014
All Microsaw Blades have been transferred to the "Declaration of Conformity" for the Surgical Dissecting Tools (CE-003, Rev. 22)		
END OF THE REVISION HISTORY		

EC DECLARATION OF CONFORMITY**MANUFACTURER**

Medtronic Powered Surgical Solutions
4620 North Beach Street
Fort Worth, TX 76137 USA

EC REPRESENTATIVE

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen, The Netherlands

PRODUCT IDENTIFIER

Electric Drill System

CUSTOMER FACING NUMBER

See Attachment A

DEVICE CLASSIFICATION

See Attachment A

CLASSIFICATION RULE

See Attachment A

CONFORMITY ASSESSMENT ROUTE

Annex II, VII

EC QUALITY SYSTEM CERTIFICATE

FM 71199

EC FULL QUALITY ASSURANCE CERTIFICATE

CE 01806

DECLARATION TYPE FOR CLASS I DEVICES

Self-Declaration: Class I Non-Sterile Devices With Non-Measuring Function

NOTIFIED BODY

BSi Management Systems America, Inc.
12110 Sunset Hills Road, Suite 200, Reston, VA 20190 USA

NOTIFIED BODY IDENTIFICATION NUMBER

0086

APPLIED STANDARDS

ISO 13485, EN 14971, EN 1041; EN 980, EN ISO 10993-1

DECLARATION STATEMENT

We, Medtronic, declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 93/42/EEC¹ which apply to them.

This declaration is supported by the EC 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.

IDENTIFICATION OF SIGNATORY**NAME****FUNCTION****SIGNATURE**

Deep Pal

Principal Regulatory Affairs Specialist

July 15, 2014

DATE OF ISSUE

15 July, 2014

LOCATION

Medtronic Powered Surgical Solutions
4620 North Beach St, Fort Worth, TX 76137 USA

¹ Including amendments issued in the years following

ATTACHMENT A: Customer Facing Number

** It should be noted that this declaration may also apply to refurbished products with a “-R” identifier as these products must conform to the same design specifications as the devices listed below. Where this is not the case, the “-R” version devices do not carry CE Marking and are not made available in the European Union.*

The CFN - Customer Facing Numbers below are covered by this Declaration of Conformance.

CFN	DESCRIPTION	STERILITY	CLASS	RULE	ANNEX	GMDN
ED500	Triton Electric High Torque Handpiece	Non-Sterile	Ila	9	II	47859
EM200	EHS Stylus Motor	Non-Sterile	Ila	9	II	47859
EM100-A	EHS Motor	Non-Sterile	Ila	9	II	47859
EM100	EHS Motor	Non-Sterile	Ila	9	II	47859
ES100	Oscillating Foot-controlled Microsaw	Non-Sterile	Ila	9	II	52749
ES110	Oscillating Finger Controlled Microsaw	Non-Sterile	Ila	9	II	52749
ES200	Reciprocating Foot-controlled Microsaw	Non-Sterile	Ila	9	II	52749
ES210	Reciprocating Finger Controlled Microsaw	Non-Sterile	Ila	9	II	52749
ES300	Sagittal Foot-controlled Microsaw	Non-Sterile	Ila	9	II	52749
ES310	Sagittal Finger Controlled Microsaw	Non-Sterile	Ila	9	II	52749
EC200	EHS Console	Non-Sterile	Ila	9	II	44491
EC100-AA01	EHS Console	Non-Sterile	Ila	9	II	44491
EC100	EHS Console	Non-Sterile	Ila	9	II	44491
EA200	EHS Motor Cable	Non-Sterile	I	1	VII	47857
EA300	EHS Foot Control Cable	Non-Sterile	I	1	VII	47857
EA600	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA601	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA602	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA603	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA604	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA605	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA606	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA607	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA608	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA609	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA610	EHS Power Cord	Non-Sterile	I	1	VII	45804
EA611	EHS Power Cord	Non-Sterile	I	1	VII	45804
EF100	EHS Foot Control	Non-Sterile	I	1, 12	VII	36336
EF105	EHS Foot Control Cover	Non-Sterile	I	1, 12	VII	36336
IRD410	Foot-controlled Microsaw Irrigation Tubing Set	Sterile	Ila	6, 11	II	36003
IRD420	Finger-controlled Microsaw Irrigation Tubing Set	Sterile	Ila	6, 11	II	36003

END OF DOCUMENT