

REVISION HISTORY**EC DECLARATION OF CONFORMITY**

TECHNICAL FILE NUMBER	CE-002	
REVISION HISTORY DESCRIPTION	REVISION	IMPLEMENTATION DATE
First Issue Product Transfer	New	September 06,2002
➤ Restructured Declaration of Conformity - Midas Rex Legend Attachments		
Previously - Pneumatic High Speed Drill System and Surgical Dissecting Tools	1	October 15, 2013
➤ AS07XOM Device Obsolescence		
➤ Addition of AT10A Attachment		
➤ Addition of Tapered Telescoping Tubes	2	February 27, 2014
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**

Midas Rex® Legend® Attachments

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 BODYBSi 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

**DATE OF ISSUE**

February 27, 2014

LOCATIONMedtronic 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 applies to refurbished products with a “-R” identifier as these products must conform to the same design specifications as the devices listed below.*

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

CFN	DESCRIPTION	STERILITY	CLASS	RULE	ANNEX	GMDN
AA07	Legend 7cm Angled Attachment (6ST)	Non-Sterile	Ila	6	II	43555
AA075	Legend 7.5cm Angled Attachment	Non-Sterile	Ila	6	II	43555
AA07XOM	Legend 7cm Angled Attachment (6ST - Xomed)	Non-Sterile	Ila	6	II	43555
AA09S	Legend 9 cm Angled Short Attachment (M)	Non-Sterile	Ila	6	II	43555
AA10	Legend 10cm Angled Attachment (9ST)	Non-Sterile	Ila	6	II	43555
AA10S	Legend 10cm Angled Short Attachment (9ST)	Non-Sterile	Ila	6	II	43555
AA14	Legend 14cm Angled Attachment (AM)	Non-Sterile	Ila	6	II	43555
AA14S	Legend 14cm Angled Short Attachment (AM)	Non-Sterile	Ila	6	II	43555
AA15	Legend 15cm Angled Attachment (A)	Non-Sterile	Ila	6	II	43555
AA-07DK	Legend Angled Double Lock Attachment, 7 cm	Non-Sterile	Ila	6	II	43555
AA-10DK	Legend Angled Double Lock Attachment, 10 cm	Non-Sterile	Ila	6	II	43555
AA-10SDK	Legend Angled Short Double Lock Attachment, 10 cm	Non-Sterile	Ila	6	II	43555
AA-15DK	Legend Angled Double Lock Attachment, 15 cm	Non-Sterile	Ila	6	II	43555
AA-09SDK	Legend Angled Short Double Lock Attachment, 9 cm	Non-Sterile	Ila	6	II	43555
AA-14DK	Legend Angled Double Lock Attachment, 14 cm	Non-Sterile	Ila	6	II	43555
AA-14SDK	Legend Angled Short Double Lock Attachment, 14 cm	Non-Sterile	Ila	6	II	43555
AC16	Legend Contra-Angle Attachment	Non-Sterile	Ila	6	II	43555
AD01	Legend Perforator Driver Attachment	Non-Sterile	Ila	6	II	43555
AD02	Legend Jacob’s Chuck	Non-Sterile	Ila	6	II	43555
AD03	Legend Perforator 1000 Driver Attachment	Non-Sterile	Ila	6	II	43555
AF01	Legend 2.4mm Foot Attachment (B5)	Non-Sterile	Ila	6	II	43555
AF02	Legend 2.4mm Foot Attachment (B1)	Non-Sterile	Ila	6	II	43555
AF03	Legend 3mm Foot Attachment (S)	Non-Sterile	Ila	6	II	43555
AF01R	Legend 2.4mm Rotating Foot Attachment (F1-B5)	Non-Sterile	Ila	6	II	43555
AF02R	Legend 2.4mm Rotating Foot Attachment (F2-B1)	Non-Sterile	Ila	6	II	43555
AR14	Legend Right Angle Attachment	Non-Sterile	Ila	6	II	43555
AS07	Legend 7cm Straight Attachment (6ST)	Non-Sterile	Ila	6	II	43555
AS075	Legend 7.5cm Straight Attachment	Non-Sterile	Ila	6	II	43555
AS08	Legend 8cm Straight Attachment (B)	Non-Sterile	Ila	6	II	43555
AS09	Legend 9cm Straight Attachment (M)	Non-Sterile	Ila	6	II	43555
AS09S	Legend 9cm Straight Short Attachment (M)	Non-Sterile	Ila	6	II	43555
AS10	Legend 10cm Straight Attachment (9ST)	Non-Sterile	Ila	6	II	43555
AS10S	Legend 10cm Straight Short Attachment (9ST)	Non-Sterile	Ila	6	II	43555
AS12S	Legend 12cm Straight Short Attachment	Non-Sterile	Ila	6	II	43555
AS14	Legend 14cm Straight Attachment (AM)	Non-Sterile	Ila	6	II	43555
AS14P	Legend 14cm Precision Graft Attachment	Non-Sterile	Ila	6	II	43555
AS14S	Legend 14cm Straight Short Attachment (AM)	Non-Sterile	Ila	6	II	43555
AS15	Legend 15cm Straight Attachment (A)	Non-Sterile	Ila	6	II	43555
AS21	Legend 21cm Straight Attachment (TU)	Non-Sterile	Ila	6	II	43555
AS26	Legend 26cm Straight Attachment (R)	Non-Sterile	Ila	6	II	43555
ASJL	Attachment, Straight, J-Latch	Non-Sterile	Ila	6	II	43555
ASMC	Legend Metal Cutting Attachment (MC)	Non-Sterile	Ila	6	II	43555
AT10	Legend Telescoping Attachment Base	Non-Sterile	Ila	6	II	43555
AT10A	AT10A Angles LGND Telescoping Base	Non-Sterile	Ila	6	II	43555
AVA07	Legend 7mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555
AVA09	Legend 9mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555
AVA10	Legend 10mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555
AVA12	Legend 12mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555

CFN	DESCRIPTION	STERILITY	CLASS	RULE	ANNEX	GMDN
AVA14	Legend 14mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555
AVA15	Legend 15mm Variable Angled Attachment	Non-Sterile	Ila	6	II	43555
AVA-07DK	Legend Angled Variable Double Lock Attachment, 7 cm	Non-Sterile	Ila	6	II	43555
AVA-10DK	Legend Angled Variable Double Lock Attachment, 10 cm	Non-Sterile	Ila	6	II	43555
AVA-12DK	Legend Angled Variable Double Lock Attachment, 12 cm	Non-Sterile	Ila	6	II	43555
AVA-15DK	Legend Angled Variable Double Lock Attachment, 15 cm	Non-Sterile	Ila	6	II	43555
AVA-09DK	Legend Angled Variable Double Lock Attachment, 9 cm	Non-Sterile	Ila	6	II	43555
AVA-14DK	Legend Angled Variable Double Lock Attachment, 14 cm	Non-Sterile	Ila	6	II	43555
AVS07	Legend 7cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS08	Legend 8cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS09	Legend 9cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS10	Legend 10cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS12	Legend 12cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS14	Legend 14cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
AVS15	Legend 15cm Variable Straight Attachment	Non-Sterile	Ila	6	II	43555
TT9	Legend Telescoping Attachment Tube - Straight	Non-Sterile	Ila	6	II	43555
TT9C	Legend Telescoping Attachment Tube - Curved	Non-Sterile	Ila	6	II	43555
TT12	Legend Telescoping Attachment Tube - Straight	Non-Sterile	Ila	6	II	43555
TT12A	Legend Telescoping Attachment Tube - Angled	Non-Sterile	Ila	6	II	43555
TT12C	Legend Telescoping Attachment Tube - Curved	Non-Sterile	Ila	6	II	43555
TT12F	Legend Telescoping Attachment Tube - Fine	Non-Sterile	Ila	6	II	43555
TT14A	Legend Telescoping Attachment Tube - Angled	Non-Sterile	Ila	6	II	43555
TT15	Legend Telescoping Attachment Tube – Straight	Non-Sterile	Ila	6	II	43555
TT15H	Legend Telescoping Attachment Tube – Hooded	Non-Sterile	Ila	6	II	43555
TT17	Legend Telescoping Attachment Tube – Straight	Non-Sterile	Ila	6	II	43555
TT18	Legend Telescoping Attachment Tube – Straight	Non-Sterile	Ila	6	II	43555
TT18H	Legend Telescoping Attachment Tube – Hooded	Non-Sterile	Ila	6	II	43555
TT12CMIS	TUBE TT12CMIS LGND 12CM TAPR TELE CURVD	Non-Sterile	Ila	6	II	43555
TT14CMIS	TUBE TT14CMIS LGND 14CM TAPR TELE CURVD	Non-Sterile	Ila	6	II	43555
TT12MIS	TUBE TT12MIS LGND 12CM TAPR TELE STRT	Non-Sterile	Ila	6	II	43555
TT12AMIS	TUBE TT12AMIS LGND 12CM TAPR TELE ANGLD	Non-Sterile	Ila	6	II	43555
TT14AMIS	TUBE TT14AMIS LGND 14CM TAPR TELE ANGLD	Non-Sterile	Ila	6	II	43555
BM100	Legend Bone Mill Attachment (Base)	Non-Sterile	I	1	VII	43555

END OF DOCUMENT