

EC DECLARATION OF CONFORMITY

SAP Title: DoC I Avenir Stem Instruments

WT-FO 327523

Revision 02

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ZIMMER BIOMET

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SAP Document: RA1-180865-E00-04

EC Declaration of Conformity

Manufacturer Zimmer GmbH
Sulzerallee 8
8404 Winterthur
Switzerland

Product (system) Name: **Avenir Hip System Instruments**

Scope: See scope list below (21 items)

Classification: Class I in accordance with rule 6, Annex IX of the Council Directive 93/42/EEC concerning medical devices.

Conformity Assessment Route: Zimmer GmbH uses the following procedures for the CE-marking of this product according to the Directive 93/42/EEC:

Class I: EC Conformity Declaration according to Annex VII

GMDN Code: 44742, Description: Joint prosthesis implantation kit, reusable

We hereby declare that the medical device(s) specified above meet the provisions of the Council Directive No. 93/42/EEC. All supporting documentation is retained at the premises of the manufacturer

Roberto Tommasini

Associate Director, Regulatory Affairs

Date (dd.mm.yyyy)

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Scope list

Article number	Product name	Class	GMDN
01.00001.001	handle for modular rasps, straight	I	44742
01.06010.910	Avenir®, base tray, plastic, empty	I	44742
01.06010.911	Avenir®, insert for plastic base tray(empty)	I	44742
70.00.01	bar, long	I	44742
70.08.89	awl	I	44742
72.13.02-10	box chisel	I	44742
75.11.00-02	handle for top	I	44742
78.00.38-28	repositioning top, ø 28	I	44742
78.00.38-32	repositioning top, ø 32	I	44742
78.00.38-36	repositioning top, ø 36	I	44742
01.06510.001	trial neck holder	I	44742
01.06010.900	Avenir®, tray for instruments, metal,empty	I	44742
01.06010.901	MIS, tray for handles, empty	I	44742
01.00029.031	tray cover (standard), grey	I	44742
00-7806-045-00	rasp handle for anterior approach	I	44742
01.00001.002	MIS, rasp handle, double offset, right	I	44742
01.00001.003	MIS, rasp handle, double offset, left	I	44742
01.06310.004	stem impactor	I	44742
78.00.38	synthetic top	I	44742
01.06808.300	extractor with sliding hammer	I	44742
5950	setting instrument with scale	I	44742

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