

REVISION 1



DECLARATION OF CONFORMITY

DePuy Orthopaedics, Inc.

PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA

Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

Product: DePuy Extremity Family **Class:** IIb
Catalog Numbers: See List of Products **File Number:** 47, Rev.1
Manufacturer: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46580-0988
U.S.A.

Notified Body Review Statement

The undersigned hereby declares that the medical devices specified above conform to the Essential Requirements (ER's) listed in **Annex I** of the EC Medical Device Directive 93/42/EEC and its relevant transposition into the national laws of Member States in which the device is intended to be placed on the market.

This declaration is supported by:

- EC quality system approval statement (Annex II) Number 0483 first issued by BSI on February 1, 1995;
- completed Essential Requirements Checklist, File Number 47, which demonstrates compliance with the ER's as listed in the EC Medical Device Directive (Annex I).

Cheryl Hastings
(Signature)
Regulatory Management Representative

7/12/00
(Date)

REVISION 1

Part No.	Product Description	D of C	MDD Class (Rule)	Sterile Method	NB
871300	RT 5DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871301	RT 10DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871302	RT 15DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871304	LT 5DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871305	LT 10DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871306	LT 15DEG HUMERAL STANDARD	12-Jul-00	Ib (Rule 8)	R	0086
871393	RT 5DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
871394	RT 10DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
871395	RT 15DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
871390	LT 5DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
871391	LT 10DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
871392	LT 15DEG HUMERAL LARGE	12-Jul-00	Ib (Rule 8)	R	0086
971171	STRD STM, RT, 4MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971172	STRD STM, LT, 4MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971167	STRD STM, RT, 6MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971168	STRD STM, LT, 6MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971169	STRD STM, RT, 9MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971170	STRD STM, LT, 9MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971160	THIN STM, RT, 4MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971161	THIN STM, LT, 4MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971163	THIN STM, RT, 6MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971164	THIN STM, LT, 6MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971165	THIN STM, RT, 9MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971166	THIN STM, LT, 9MM INS, ULNAR-STD	12-Jul-00	Ib (Rule 8)	R	0086
971203	STRD STM, RT, 4MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971202	STRD STM, LT, 4MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971205	STRD STM, RT, 6MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971204	STRD STM, LT, 6MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971207	STRD STM, RT, 9MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971206	STRD STM, LT, 9MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971209	THIN STM, RT, 4MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971208	THIN STM, LT, 4MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971211	THIN STM, RT, 6MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971210	THIN STM, LT, 6MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971213	THIN STM, RT, 9MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
971212	THIN STM, LT, 9MM INS, ULNAR-LG	12-Jul-00	Ib (Rule 8)	R	0086
112806050	GLOBAL FX PC STEM 6MM	12-Jul-00	Ib (Rule 8)	R	0086
112806060	GLOBAL FX PC STEM 6MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
112808050	GLOBAL FX PC STEM 8MM	12-Jul-00	Ib (Rule 8)	R	0086
112808060	GLOBAL FX PC STEM 8MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
112810050	GLOBAL FX PC STEM 10MM	12-Jul-00	Ib (Rule 8)	R	0086
112810060	GLOBAL FX PC STEM 10MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
112812050	GLOBAL FX PC STEM 12MM	12-Jul-00	Ib (Rule 8)	R	0086
112812060	GLOBAL FX PC STEM 12MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
112910000	ROCKWOOD CLAVICLE IM PIN 2.5MM	12-Jul-00	Ib (Rule 8)		0086
112910051	ROCKWOOD CLAVICLE PIN NUT 2.5MM	12-Jul-00	Ib (Rule 8)		0086
112910052	REDUCED DIAMETER CLAVICLE PIN NUT, 2.5MM	12-Jul-00	Ib (Rule 8)		0086

Part No.	Product Description	D of C	MDD Class	Sterile Method	NB
112912000	ROCKWOOD CLAVICLE IM PIN, 3.0MM	12-Jul-00	Ib (Rule 8)		0086
112912051	ROCKWOOD CLAVICLE PIN NUT, 3.0MM	12-Jul-00	Ib (Rule 8)		0086
112912052	REDUCED DIAMETER CLAVICLE PIN NUT, 3.0MM	12-Jul-00	Ib (Rule 8)		0086
112914000	ROCKWOOD CLAVICLE IM PIN, 3.8MM	12-Jul-00	Ib (Rule 8)		0086
112914051	ROCKWOOD CLAVICLE PIN NUT, 3.8MM	12-Jul-00	Ib (Rule 8)		0086
112914052	REDUCED DIAMETER CLAVICLE PIN NUT, 3.8MM	12-Jul-00	Ib (Rule 8)		0086
112916000	ROCKWOOD CLAVICLE IM PIN, 4.5MM	12-Jul-00	Ib (Rule 8)		0086
112916051	ROCKWOOD CLAVICLE PIN NUT, 4.5MM	12-Jul-00	Ib (Rule 8)		0086
112916052	REDUCED DIAMETER CLAVICLE PIN NUT, 4.5MM	12-Jul-00	Ib (Rule 8)		0086
113706050	GLOBAL ADVANTAGE PC STEM, 6MM	12-Jul-00	Ib (Rule 8)	R	0086
113706060	GLOBAL ADV PC STEM, 6MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
113708050	GLOBAL ADVANTAGE PC STEM, 8MM	12-Jul-00	Ib (Rule 8)	R	0086
113708060	GLOBAL ADV PC STEM, 8MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
113710050	GLOBAL ADVANTAGE PC STEM, 10MM	12-Jul-00	Ib (Rule 8)	R	0086
113710060	GLOBAL ADV PC STEM, 10MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
113712050	GLOBAL ADVANTAGE PC STEM, 12MM	12-Jul-00	Ib (Rule 8)	R	0086
113712060	GLOBAL ADV PC STEM, 12MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
113714050	GLOBAL ADVANTAGE PC STEM, 14MM	12-Jul-00	Ib (Rule 8)	R	0086
113714060	GLOBAL ADV PC STEM, 14MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
113716050	GLOBAL ADVANTAGE PC STEM, 16MM	12-Jul-00	Ib (Rule 8)	R	0086
113716060	GLOBAL ADV PC STEM, 16MM LONG	12-Jul-00	Ib (Rule 8)	R	0086
123300000	NEUFLEX PIP IMPLANT SZ. 0	12-Jul-00	Ib (Rule 8)	G	0086
123310000	NEUFLEX PIP IMPLANT SZ. 10	12-Jul-00	Ib (Rule 8)	G	0086
123320000	NEUFLEX PIP IMPLANT SZ. 20	12-Jul-00	Ib (Rule 8)	G	0086
123330000	NEUFLEX PIP IMPLANT SZ. 30	12-Jul-00	Ib (Rule 8)	G	0086
123340000	NEUFLEX PIP IMPLANT SZ. 40	12-Jul-00	Ib (Rule 8)	G	0086
123350000	NEUFLEX PIP IMPLANT SZ. 50	12-Jul-00	Ib (Rule 8)	G	0086
123360000	NEUFLEX PIP IMPLANT SZ. 60	12-Jul-00	Ib (Rule 8)	G	0086
155501020	AGILITY FLANGE TALAR SZ1	12-Jul-00	Ib (Rule 8)	R	0086
155505020	AGILITY FLANGE TALAR SZ5	12-Jul-00	Ib (Rule 8)	R	0086
155506020	AGILITY FLANGE TALAR SZ6	12-Jul-00	Ib (Rule 8)	R	0086
193420000	ROCKWOOD SHOULDER SCREW WASHER	12-Jul-00	Ib (Rule 8)		0086
193430000	ROCKWOOD SHOULDER SCREW 30MM	12-Jul-00	Ib (Rule 8)		0086
193435000	ROCKWOOD SHOULDER SCREW 35MM	12-Jul-00	Ib (Rule 8)		0086
193440000	ROCKWOOD SHOULDER SCREW 40MM	12-Jul-00	Ib (Rule 8)		0086
193445000	ROCKWOOD SHOULDER SCREW 45MM	12-Jul-00	Ib (Rule 8)		0086
193450000	ROCKWOOD SHOULDER SCREW 50MM	12-Jul-00	Ib (Rule 8)		0086



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VYHLÁSENIE O ZHODE

Výrobok:	CXKH\j XMRV\ 6 L@ _ 7 ^ZLT PZ	Trieda:	::I
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Slovenská republika

PREKLADATEĽSKÁ DOLOŽKA

Preklad som vypracovala ako prekladateľka zapísaná v zozname znalcov, tlmočníkov a prekladateľov, ktorý vedie Ministerstvo spravodlivosti Slovenskej republiky v odbore slovenský jazyk – anglický jazyk, evidenčné číslo prekladateľa 970866.

Prekladateľský úkon je zapísaný v prekladateľskom denníku č. 1/2012 pod poradovým číslom *192* /2012.

Za prekladateľský úkon a vzniknuté náklady účtujem podľa vyúčtovania na základe dokladu č. *14* /2012.

V Bratislave dňa *20.2.* 2012



TRANSLATOR'S CLAUSE:

I have translated the source document as a translator registered in the List of Experts, Interpreters and Translators maintained by the Ministry of Justice of the Slovak Republic, in the field Slovak - English Translations, under Translator's Reg. No. 970866.

The translation is registered in the Translator's Diary No. 1/2012 under No. *192* /2012.

I charge you for the translation and the costs incurred on the basis of document No. *14* /2012

In Bratislava on *20.2.* 2012



