Posey®

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Declaration of Conformity

Manufacturer:	Posey Products LLC Posey Company 5635 Peck Road Arcadia, CA 91006 – U.S.A. Phone: 626-443-3143 Fax: 626-443-5014
European Representative	Medical Device Safety Service GmbH Schiffgaben 41 30175 Hannover - Germany Telephone: 49 511 62628630 Fax: 49 511 62628633
Conformity Assessment Procedure:	Annex VII
Technical File No.:	TF-0003
Product:	Posey Soft Limb Restraints and Holders
Model Numbers:	1035, 1040, 2510, 2520, 2526, 2528, 2530, 2531, 2532/A, 2533, 2534, 2540, 2541, 2550, 2551/A, 2552, 2554, 2625, 2631, 4642, 4643, 4660, 4733, 4734, 4749, 6550, 6554/P, 8141, 8142, 8143, 8161, 8162, 8166, 8167, 8168, 8169, 8170, 8196, 8197, 25251, and 25281.
Device Classification:	Class I, Non-Sterile, Non-Measuring Medical Device (as Rule 1 in MDD Annex IX)
Intended Use:	The Posey Soft Limb Products are intended for restricting limb movement in patients who disrupt medical treatment.

The manufacturer hereby declares that the above-mentioned medical device complies with the European Medical Devices Directive 93/42/EEC as amended by directive 2007/47/EC, and its relevant transposition into national laws of the member states into which we place the devices. The medical devices are self-certified according to the principles of an ISO 13485:2003 Quality Management System with Certificate of Registration, FM 40807.

Signed in Arcadia, California, USA

	Name	**Date**
Approval:		April 24 2017
Bonnie Bishop, VP of Quality Assurance & Regulatory Affairs		