Ranfac

Precision instruments for specialized applications

April 29, 2014

EC – DECLARATION OF CONFORMITY

We, the Predident and his Executive Staff of Ranfac Corp., with corporate Offices and Manufacturing Facility located at 30 Doherty Avenue, P.O. Box 635, Avon, Massachusetts 02322-0635 USA, being the Manufacturer and Distributor of: Cholangiography Catheters, Suturing and Hypodermic Needles, Breast Care Systems, Oral Care Products, Laparoscopic Surgery Devices, Suture Graspers and Soft Tissue Biopsy Needles with European Community Representation by Novamedisan Italia S.r.l., Via dei Lapidari, 3, 40129, Bologna, ITALY along with Bone Marrow Biopsy Needles & Kits including Snarecoil® Bone Marrow Biopsy Needles & Kits and Aspiration Needles & Kits with European Community Representation by Mermaid Medical A/S, Frydensbergveg 25, DK-3660 Stenloese, DENMARK, and the Blue Suture Grasper with European Community Representation by Blue Surgical ApS, Virumveg 64, DK-2830 Virum, DENMARK, and the Mediflex Suture Grasper with European Community Representation by Baty International, Victoria Road, Burgess Hill, West Sussex, RH15 9LR, ENGLAND, declare effective April 29, 2014 that the above are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, ANNEX I, ANNEX V, and ANNEX VII in ISO 13485:2003. Under the supervision of the British Standards Institution, a Notified Body authorized by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086. The relevant Statutory Instrument is SI 1994/3017 as amended by SI 2002/618.

This Declaration is upon signature below.

Robert M. Adler
PRESIDENT

Barry Zimble
GENERAL MANAGER

Christopher P. Whelan
SENIOR V.P. REGULATORY

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