



Precision instruments for specialized applications

September 06, 2016

EC – DECLARATION OF CONFORMITY

We, the President and his Executive Staff of Ranfac Corp., with corporate Offices and Manufacturing Facility located at 30 Doherty Avenue, PO Box 635, Avon, Massachusetts 02322-0635 USA, being Manufacturer and Distributor of:

Model No.	Trade Name	MDD 93/42/EEU Classification & Rule
MC-RAN-11C	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
MC-RAN-11CSTS	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
MC-RAN-8	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
MC-RAN-8STS	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
MC-RAN-13C	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
MC-RAN-13K9	MC-RAN Bone Marrow Aspiration System	Class IIa, Article 9, Annex IX, Rule# 6
RAN-11(11/15/N/B)	Ranfac Bone Marrow Aspiration Needle	Class IIa, Article 9, Annex IX, Rule# 6
RAN-8(15/N/B)	Ranfac Bone Marrow Aspiration Needle	Class IIa, Article 9, Annex IX, Rule# 6
RAN-15/15-4	Ranfac Bone Marrow Aspiration Needle	Class IIa, Article 9, Annex IX, Rule# 6
RAN-16	Ranfac Bone Marrow Aspiration Needle	Class IIa, Article 9, Annex IX, Rule# 6
RAN-FILTER	Ranfac Filter Assembly	Class IIa, Article 9, Annex IX, Rule# 2

with European Community Representation by ASPIRE Medical Innovation GmbH, Einsteinstr. 167, 81677, Munich, Germany, declare effective August 17, 2016 that the above is 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 with Certificate No. FM 72922 since 02/13/2003 and CE Certificate No. CE 01760 since 22 JAN 1998. 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. All relevant standards are adhered to in the design, development, testing, manufacture, sterilization and inspection of the product. This Declaration is upon signature below.

Robert M. Adler
President

Barry H. Zimble
Executive Vice President / General Manager

Harlan L. Adler
Vice President of Sales & Marketing

Christopher P. Whelan
Senior Vice President – R/A
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