EC-DECLARATION OF CONFORMITY

83001-30 BONE MARROW ASPIRATION NEEDLES
RAN and MC-RAN

This declaration of conformity is issued under the sole responsibility of Ranfac Corporation

MANUFACTURER		
Name of Company	**Address**	**SRN**
Ranfac Corp.	Ranfac Corporation 30 Doherty Avenue Avon, MA, USA	US-MS-000008871

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
POPULATE WITH NAME	POPULATE WITH MODEL(S)
74047-04M	RAN-154
74062-02M	RAN-11
74174-01M	RAN-815NRT-BEV
74174-15M	RAN-815N
74230-01M	RAN-11B
74274-01M	RAN-811-OT
74276-05M	RAN-811-CT
74313-01M	RAN-1115
74333-01M	RAN-1311H-OT
74354-01M	RAN-1115N5B
74368-01M	RAN-1113-OT

74386-01M	CER-SUB-825-M
74392-15M	RAN-1115H5T-BNT
74303-01M	MC-RAN-11C
74304-01M	MC-RAN-8C
74402-01M	MC-RAN-11CSTS
74395-01M	CER-EXT
74396-01M	CER-ORTHO
74397-01M	CER-LA
74398-01M	CER-FLEX
74400-01M	CER-EXT-M
74399-01M	CER-ORTHO-M
74401-01M	CER-LA-M
74360-01M	CER-SUB-83N
74362-01M	CER-SUB-1111-OT
74363-01M	CER-SUB-1112-CT
74364-01M	CER-SUB-1560
74385-01M	CER-SUB-825
74386-01M	CER-SUB-825-M
74387-01M	CER-SUB-1111-OT-BNT
Intended Purpose	**Basic UDI-DI**
POPULATE WITH INTENDED PURPOSE The RAN Bone Marrow Aspiration Needle is intended for use in aspirating a bone marrow specimen. The MC-RAN Bone Marrow Aspiration Needle is intended for aspiration of bone marrow or autologous blood using a standard piston syringe.	POPULATE WITH BASIC UDI-DI 08586900068300101G5

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	IIa	SEE PAGE 4 FOR LIST OF STANDARDS AND COMMON SPECIFICATIONS
Rule:	6	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)/ Expiration date**
BSI Group America Inc. 12950 Worldgate Drive, Suite 800 Hendon, VA 20170-6007 USA	2797	EC conformity declaration according to Annex IX,	**MDR 761263** Expiration Date: 2028-01-12

Ranfac Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

EC-DECLARATION OF CONFORMITY

COMPANY REPRESENTATIVE/ PRRC: Eric Kreuz

TITLE: VP of QA/RA

SIGNATURE: Eric Kreuz
Eric Kreuz (Jan 27, 2023 15:54 EST)

PLACE: 30 Doherty Ave, Avon MA 02322

DATE: Jan 27, 2023

Common Specification and Standards applied in full or in part.

EN ISO 13845:2016	Medical Devices – Quality Management Systems - Requirements for Regulatory Purposes
BS EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects—Good clinical practice
MEDDEV 2.7.1/rev.4 (June 2016)	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
EN 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
ISO 80639-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
ISO 11135-1:2014	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation & Testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity
ISO 10993-11:2017	Biological evaluation of medical devices- Part 11: Tests for systemic toxicity

EN ISO 10993-12:2012	Biological evaluation of medical devices- Part 12: Sample preparation and reference materials
EN ISO 10993-7:2008	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO 11607-1:2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2: 2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISTA 2A:2011	Partial Simulation Performance Testing for Packaged Products 150lbs or less.
ASTM F1980:2017	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
AAMI/ANSI/ISO 11138-2:2017	Sterilization of health care products - Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization process
ISO 11737-1:2006/2011	Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products
ISO 11737-2:2018	Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility in the definition, validation and maintenance of a sterilization process
AAMI ST72 2011/2016	Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing
BS-EN-ISO-15223-1 2021 EDITION	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
BS-EN-ISO-20417:2021	Information supplied by the manufacturer of medical devices

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Final Audit Report 2023-01-27

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