RANFAC CORP	# Declaration TITLE: EC-Declaration of Conformity 83007-30 Ranfac Biopsy Needles (RBN,RTN)	DOCUMENT #: 83007-30 REVISION #: C PAGE: Cover page ISSUED/REVISED PER ECO #: 23190

WRITTEN/REVISED BY: Bridgette Bowyer Bridgette Bowyer (Aug 18, 2023 15:51 EDT) DATE:_____

REVIWED BY: Eric Kreuz Eric Kreuz (Aug 18, 2023 15:53 EDT) DATE:_____

REVISION RECORD

Previous ECOs:

Revision Number	ECO Number	Description of Changes
A	**23012**	Initial Release of MDR complaint Declaration of Conformity for RBN, and RTN.
B	**23120**	Change Route to Conformity for the products to Annex IX Ch. I & III. Change in the AR (Emergo Europe) address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands. Change in the NB Address to BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands.
C	**23190**	Addition of part numbers 74361-01M and 74366-01M

EC-DECLARATION OF CONFORMITY

83007-30 Bone Marrow Biopsy Needles (RBN, RTN)

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, 02322 USA	US-MF-000008871

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION				
Catalogue Number	Part Number	Description		
RBN-116	74049-02M	11	6”	No ports, packaged in Tyvek pouch, 10 each/box
RBN-86	74049-07M	8	6”	No ports, packaged in Tyvek pouch, 10 each/box
RBN-114	74050-01M	11	4”	No ports, packaged in Tray, 10 each/box
RBN-133	74050-03M	13	3”	No ports, packaged in Tray, 10 each/box
RBN-132	74050-05M	13	2”	No ports, packaged in Tray, 10 each/box
RBN-84	74050-06M	11	4”	No ports, packaged in Tray, 10 each/box
RBN-114S	74092-01M	11	4”	No ports, packaged in Tray, 10 each/box

RBN-116S	74093-02M	11	6”	No ports, packaged in Tyvek pouch, 10 each/box
RBN-84	74224-01M	8	4”	No ports, packaged in Tray, 10 each/box
RBN-86	74225-01M	8	6”	No ports, packaged in Tyvek pouch, 10 each/box
RBN-84	74367-01M	8	4”	No ports, packaged in Tyvek pouch, 10 each/box
RTN-84-T	74211-01M	8	4”	No ports, packaged in Tray, 10 each/box
RTN-86-T	74212-01M	8	6”	No ports, packaged in Tyvek pouch, 10 each/box
RTN-114-T	74213-01M	11	4”	No ports, packaged in Tray, 10 each/box
RTN-116-T	74214-01M	11	6”	No ports, packaged in Tyvek pouch, 10 each/box
CER-BN-84	74361-01M	8	4”	No ports, packaged in Tyvek pouch, 1 per box
CER-BN-116	74366-01M	11	6”	No ports, packaged in Tyvek pouch, 1 per box

Intended Purpose	**Basic UDI-DI**	
The Bone Marrow Biopsy Needle is intended for the purpose of harvesting bone marrow specimens.	08586900068300701H3	

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	IIa	SEE PAGE 2 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 The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, The Netherlands	2797	Regulation (EU) 2017/745, Annex IX, Ch. I & III	**MDR 761263 R000** 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

COMPANY REPRESENTATIVE/ PRRC: Eric Kreuz

TITLE: VP of QA/RA
SIGNATURE: Eric Kreuz
Eric Kreuz (Aug 18, 2023 15:53 EDT)

PLACE: **30 Doherty Ave, Avon MA 02322**
DATE:

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