By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761263 R000

Manufacturer: Ranfac Corporation

Address:
30 Doherty Avenue
Avon
Massachusetts
02322
USA

Single Registration Number: US-MF-000008871

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-01-13**

Current Issue Date: **2025-05-09**

Starting Validity Date: **2025-05-09**

Expiry Date: **2028-01-12**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Suture Grasper	Class IIa
Bone Marrow Aspiration Needle	Class IIa
Marrow Cellution Aspiration Needle	Class IIa
Bone Marrow Biopsy Needle	Class IIa
Platelet Separator Devices	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-13	3576596	Issued
2024-03-21	30118219	Amended – Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.
Current	30163237	Supplemented – Addition of Platelet Separator Devices

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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