

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

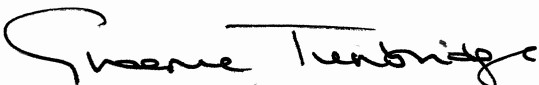
Address:

Prinsessegracht 20
2514 AP The Hague
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 and Class IIb implantable devices an 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 Medical Devices

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

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

Starting Validity Date: **2023-01-13**

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



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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
Current	3576596	Issued



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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.