EC CERTIFICATE

Number: 4201663CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:

Matrix Cell Research Institute Inc.

5th Azuma Bldg., 3-38 Kanda Sakuma-cho Chiyoda
Tokyo 101-0025
Japan

For the product category(ies)

Magnetometers for detection of magnetic fluid used to identify cancer metastases in Sentinel Lymph Node and detection of magnetic markers deployed in the non-palpable lesions and soft tissue tumor types in the breast cancer surgeries

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 4201663CN, initially dated 1 July 2019
Addendum, initially dated 1 July 2019

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 1 July 2019
Revised: 5 February 2021
DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 4201663CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Magnetometers for detection of magnetic fluid used to identify cancer metastases in Sentinel Lymph Node and detection of magnetic markers deployed in the non-palpable lesions and soft tissue tumor types in the breast cancer surgeries

Issued to:

Matrix Cell Research Institute Inc.
5th Azuma Bldg., 3-38 Kanda Sakuma-cho Chiyoda
Tokyo 101-0025
Japan

This certificate covers the following product(s):

MagProbe TAKUMI (class IIa)

Initial date: 1 July 2019
Revision date: 5 February 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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