

Number: 2267926CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Comecer Netherlands B.V.

Madame Curieweg 1

8501 XC Joure

The Netherlands

SRN ID.: NL-MF-000026292

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 EU- Regulation which apply to them:

0344

Supplement to certificate: 2109295CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

Managing Director

Principal Certification Manager

First Issued: **24 February 2023**

Date: **11 September 2024**

Expiry date: **1 February 2028**

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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
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Other active non-implantable devices (MDA0318, Class Im)

Device Name : Radionuclide Dose Calibrator

1. RDC-VIK-202

(comprising of Ionization Chamber VIK-202, IBC-Lite Software Readout or DoseApp Rel. 2024.x.y)

2. RDC-VIK-203

(comprising of Ionization Chamber VIK-203, IBC-Lite Software Readout or DoseApp Rel. 2024.x.y)

3. RDC-TRSF-001

(comprising of Ionization Chamber TRSF-001, IBC-Lite Software Readout or DoseApp Rel. 2024.x.y)

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Conditions for or limitations to the validity of this certificate:

- For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	24-02-2023	2109295CN17	First issue
1	17-05-2023	2109295CN18	Revised
2	11-09-2024	2109295CN19	Revised

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