

DECLARATION OF CONFORMITY

**We, Manufacturer**

Comecer Netherlands B.V.
Madame Curieweg 1,
8501 XC Joure, the Netherlands

Single Registration Number (SRN)

NL-MF-000026292

Declare under our sole responsibility that the**Radionuclide Dose Calibrator**

Basic UDI-DI: 8719324589RDCJU

Covering following device

Name	Models	Product code	UDI- DI (GTIN-14)
Radionuclide dose calibrator	RDC-VIK-202	0202020160	08719324589000
	RDC-VIK-203	0202020161	08719324589017
	RDC-TRSF-001	0202020088	08719324589079

According to

CE certificate 2267926CE01 Annex IX chapter 1 and 3, issued by DEKRA Certification B.V., the Netherlands, Notified Body Identification Number 0344

Are in conformity with the following regulation

European Regulation (EU) 2017/745 on Medical Devices

Risk class of the device

Medical Device Class Im, in accordance with Annex VIII classification rules 13

Common Specification to which conformity is declared

Nonapplicable

Quality management system certification

According EN-ISO 13485:2016 by DEKRA Certification B.V., the Netherlands, certificate number 2182264

Place

Joure, The Netherlands

Date of issue

2024/07/17

Name and function

Domenico Sainato, Managing Director

Signature on behalf of Comecer Netherlands B.V

17/07/2024

x Domenico Sainato