

CERTIFICATE

Number: 2182264

The management system of:

Comecer Netherlands B.V.

Madame Curieweg 1
8501 XC Joure
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

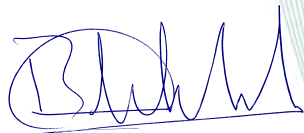
Design, development, manufacture, distribution, installation and service of ionizing radiation measuring devices and dispensing and injection systems for radiopharmaceuticals for the areas of radiodiagnostics and radiotherapy

Certificate expiry date: 1 September 2024

Certificate effective date: 1 September 2021

Certified since: 13 October 2015

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DICHIARAZIONE DI CONFORMITA' CE EC-DECLARATION OF CONFORMITY

(LVD and EMC)

L'azienda dichiara che I prodotti specificati in basso sono conformi alle disposizioni di:

- Direttiva Bassa Tensione (LVD) 2014/35/EU
- Direttiva sulla Compatibilità elettromagnetica (EMC) 2014/30/EU.
- Direttiva sui rifiuti elettrici ed elettronici 2012/19/EU
- Direttiva sulle restrizioni nell'uso di sostanze pericolose contenute nei component elettrici ed elettronici (EU) 2015/863

We hereby declare that the products specified below meet the relevant provisions of

- *the Low Voltage Directive (LVD) 2014/35/EU*
- *the Directive of Electromagnetic Compatibility (EMC) 2014/30/EU.*
- *The Directive Waste of Electronical and Electrotechnical Equipment 2012/19/EU*
- *The Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EU) 2015/863*

Questa dichiarazione di conformità si riferisce agli articoli con marchio CE prodotti da:

This Declaration of Conformity covers the following CE marked products manufactured by:

Produttore/Manufacturer:

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

Categoria di prodotto/Product Category:

Monitore di contaminazione personale /Personal Contamination Monitors

Nome prodotto Product name	Modelli Models	Product code Codice Prodotto	SN# and up N° NS e successivi
Monitor mani-piedi-vesti Hand-Foot-Clothing Monitor	VLB-202	0207050001	201505 _ _ _ _
	VLB-202H	0207050002	
	VLB-202CH	0207050007	
	VLB-303-2	0207050010	
	VLB-303-2-CH	0207050012	
	VLB-303-4	0207050011	

Questa dichiarazione di conformità viene rilasciata sotto la responsabilità esclusiva del produttore.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

La progettazione e costruzione di questi prodotti è conforme con agli standard armonizzati
The design and construction of this product is in accordance with the harmonized standard:

NEN-EN-IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use Prescrizioni di sicurezza per apparecchi elettrici di misura, controllo e per utilizzo in laboratorio Parte 1: Prescrizioni generali
NEN-EN-IEC 61326-1:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements Apparecchi elettrici di misura, controllo e laboratorio - Prescrizioni di compatibilità elettromagnetica - Parte 1: Prescrizioni generali
NEN-EN-IEC 61098:2007	Radiation protection instrumentation – Installed personnel surface contamination monitoring assemblies Strumentazione per la radioprotezione - Apparecchi fissi per il controllo della contaminazione radioattiva della superficie corporea

15/09/2020

X Domenico Sainato

D. Sainato
Managing Director
Signed by: Domenico Sainato

Le attrezzature Comecer prodotte per il mercato Nord Americano non sono certificate da laboratory UL o CSA.
Tuttavia, il processo di produzione e la selezione dei componenti sono effettuati allo scopo di includere, dove possibile, il componente commerciale già certificato per il mercato Nord Americano (UL/CSA)

*Comecer equipment manufactured for the North American market are not certified by UL or CSA Laboratory.
However, the manufacturing technology and the component selection has been performed with the aim to have, when it's possible, the commercial components already certified for the North American market (UL/CSA)*

CERTIFICATE

Number: 2227863

The management system of:

Comecer Netherlands B.V.

Madame Curieweg 1
8501 XC Joure
The Netherlands

including the implementation meets the requirements of the standard:

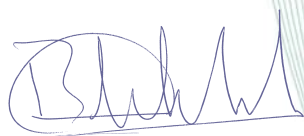
ISO 9001:2015

Scope:

Design, Manufacture, Sales, Installation and service of instruments, equipment, software and accessories for nuclear medicine and (nuclear) industry.

Certificate expiry date: 1 September 2024
Certificate effective date: 1 September 2021
Certified since*: 13 September 2002

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



M.G.G. Boersma
Certification Manager

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