MiE medical imaging electronics

EC-Declaration of Conformity

according to Directive 93/42/EEC, Annex II excluding section (4)

MiE medical imaging electronics GmbH

represented by the presidents Thomas Kühl and Günther W. Kühl

declares in own responsibility that following described system fulfills the requirements of Annex I of the Directive 93/42/EEC.

Manufacturer:	MiE medical imaging electronics GmbH Hauptstr. 112, D-23845 Seth, Germany Tel.: +49 4194 9977-0 mie@miegermany.de Fax: +49 4194 9977-55 www.mie-scintron.com
Product Name:	**System ECAM - SCINTRON**
Product Description:	Anger type of whole-body and SPECT Gamma-Camera with one alt. two high resolution rectangular detectors and Nuclear Medicine Workstation for the whole nuclear medicine diagnostic
Classification:	Class IIa (according to Rule 10 of Annex IX to Council Directive 93/42/EEC)
Validity:	This Declaration of Conformity is valid until 26.05.2024
Name and Address of Notified Body:	DEKRA Certification GmbH Handwerkstraße 15 D-70565 Stuttgart, Germany
Notified Body number:	0124
Quality Management System:	EN ISO 13485:2016/AC:2016 Medical Devices – Quality Management Systems – Requirements for regulatory purposes

Seth, 20.05.2021

Date

Signature President