Declaration of conformity to Regulation (EU) 2023/607

Status: freigegeben

MiE medical imaging electronics GmbH

Represented by Mr. Thomas Kühl as the Managing Director

Declares, under its sole responsibility, that MiE medical imaging electronics GmbH has applied the transitional provisions of Article 120 of Regulation (EU) 2017/745 (MDR) in its current version / or Regulation (EU) 2023/607.

Manufacturer's name and contact details:	MiE medical imaging electronics GmbH Hauptstraße 112 23845 Seth Phone: +49 4194 9977-0 Fax: +49 4194 9977-0 Email: mie@miegermny.de Homepage: www.mie-scintron.com
Single Registration Number (SRN):	DE-MF-000005311
Notified Body (Directive 93/42/EEC):	DEKRA Certification GmbH
Identification number of the Notified Body:	0124
Number of the referenced Directive Certificate:	50862-16-05
Original expiry date as indicated on the directive certificate before the extension of validity:	2024-05-26
End date of the extended validity/transition period:	December 31, 2028

In this context, the following is particularly confirmed:

a) The systems listed below (Annex 1 - Product List) continue to comply with Directive 93/42/EEC.
b) There have been no significant changes in the design and intended purpose of these products, nor are any such changes planned.
c) The products do not present an unacceptable risk to the health or safety of patients, users, or other individuals, or to other aspects of public health protection.
d) MiE medical imaging electronics GmbH has established a quality management system in accordance with Article 10(9).
e) MiE medical imaging electronics GmbH submitted a formal application for conformity assessment for the listed systems to a Notified Body on November 30, 2023, in accordance with Annex VII Section 4.3 subparagraph 1 of the MDR.
f) The Notified Body and MiE medical imaging electronics GmbH signed a written agreement no later than September 26, 2024, in accordance with Annex VII Section 4.3 subparagraph 2 of the MDR.

The fulfillment of these requirements extends the validity of the EU certificate issued on July 16, 2019, with validity until May 26, 2024 (certificate number: 50862-16-05), in accordance with Article 120(2), subparagraph 2 of the MDR, in conjunction with Article 120(3a), letter b), by law until December 31, 2028.

Annex 1 - Product List

The above statement applies to the following systems:

Identification of the device(s)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
PICOLA – SCINTRON (Class IIa, MD 1201, Gamma Camera Systems)	50862-16-05	2024-05-26	DEKRA Certification GmbH, 0124	TÜV NORD CERT GmbH, 0044	December 31, 2028	Not applicable
SYNGULA – SCINTRON (Class IIa, MD 1201, Gamma Camera Systems)	50862-16-05	2024-05-26	DEKRA Certification GmbH, 0124	TÜV NORD CERT GmbH, 0044	December 31, 2028	Not applicable
ECAM – SCINTRON (Class IIa, MD 1201, Gamma Camera Systems)	50862-16-05	2024-05-26	DEKRA Certification GmbH, 0124	TÜV NORD CERT GmbH, 0044	December 31, 2028	Not applicable
DIACAM – SCINTRON (Class IIa, MD 1201, Gamma Camera Systems)	50862-16-05	2024-05-26	DEKRA Certification GmbH, 0124		December 31, 2028	Not applicable
SCINTRON (Class IIa, MD 1201, Scintron Workstation)	50862-16-05	2024-05-26	DEKRA Certification GmbH, 0124	TÜV NORD CERT GmbH, 0044	December 31, 2028	Not applicable