EU Quality Management System Certificate FI25/00000027

The management system of

Spellman High Voltage Electronics GmbH

Address: Spellman High Voltage Electronics GmbH, Josef-Baumann-Straße 23, 44805 Bochum, Germany
SRN: DE-MF-000014609
has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products
High voltage X-ray generators

Certification is based on decision FI25/08183P0
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, their intended purposes, risk classification, standards and common specifications followed, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 04 April 2025 until 03 April 2030 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 04 April 2025
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Teuvo Vaara, Certifier

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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

Spellman High Voltage Electronics GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1
Sites
Spellman High Voltage Electronics GmbH Josef-Baumann-Straße 23 44805 Bochum, Germany High voltage X-ray generators

Spellman High Voltage Electronics GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Attachment 1 of Issue 1

Device or Device Group, EMDN Code	Risk Class	Identification Details and Intended Purposes
Z11039011 – High voltage X-ray generators	IIb	Medical X-Ray Generator Models: EDITOR HFe 401 alternative names: PROVARIO HF 40, OptiX 40 HF EDITOR HFe 501 alternative names: PROVARIO HF 50, OptiX 50 HF EDITOR HFe 601 alternative names: PROVARIO HF 60, OptiX 60 HF EDITOR HFe 801 alternative names: PROVARIO HF 80, OptiX 80 HF Intended Purpose: The product is intended to be used in medical X-ray diagnostic / image guidance systems. It is one part of an X-ray system, which is assembled by a systems integrator. It provides power to the X-ray tubes and provides interfaces for X-ray Imaging Systems.

The certification decision is based on the following:

Report Identification and Date
Audit report: Spellman - V1-S2 - FPMDREG3019 - MD Audit Report Ver G 20250325, dated 2025-03-25 TDA report: Spellman V1 FPMDREG3020 - MDR Technical Documentation Assessment Report Ver G 20250325, dated 2025-03-25

Applied Standards / Common specifications
EN ISO 13845:2016+A11/2021 EN ISO 14971:2019+A11/2021 EN ISO 15223-1:2021 References to relevant common specifications or harmonized standards are in the reports where applicable.

Conditions for or limitation to the validity of the certificate
N/A

EU Authorised Representative
N/A, the manufacturer is in the EU