# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60144934 0001

**Report No.:** 21237472 014

**Manufacturer:**
Spellman High Voltage
Electronics GmbH
Josef-Baumann-Str. 23
44805 Bochum
Deutschland

**Products:**
X-ray generators

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60106232 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-12-03

**Date:** 2019-12-03

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH

TÜVRheinland

Prüfungsstelle

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** HD 60144934 0001
**Report No.:** 21237472 014

**Manufacturer:** Spellman High Voltage Electronics GmbH
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44805 Bochum
Deutschland

Products included:

- EDITOR HFe 401 alternative: PROVARIO HF 40, OptiX 40 HF
- EDITOR HFe 501 alternative: PROVARIO HF 50, OptiX 50 HF
- EDITOR HFe 601 alternative: PROVARIO HF 60, OptiX 60 HF
- EDITOR HFe 801 alternative: PROVARIO HF 80, OptiX 80 HF

**Notified Body**

**Date:** 2019-12-03

**Roland Gruber**

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle