

# EC Certificate

**Full Quality Assurance System**  
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1504254-1

Manufacturer: Hutz Lighting Technique 1986  
(PTY) Limited  
26 Henry Ford Road  
6020 Port Elizabeth  
South Africa

Products: Medical supply units

Replaces EC Certificate number HD 60117413 0001

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.

Report No.: 26300346 008

Effective date: 2020-11-16

Expiry date: 2024-05-26

Issue date: 2020-11-16



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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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The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Hutz Lighting Technique 1986 (PTY) Limited 26 Henry Ford Road 6020 Port Elizabeth South Africa	Activity: Design and manufacture of medical supply units
/02	Hutz Hospi-Tec (PTY) Limited 26 Henry Ford Road 6020 Port Elizabeth South Africa	Activity: Manufacture of medical supply units

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