# EC CERTIFICATE

## simex Medizintechnik GmbH

Brückstraße 30/1
78652 Deißlingen-Lauffen
Germany

## Full Quality Assurance System Approval Certificate

Annex II (excluding section 4.0) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:
**Manufacture and supply of medical suction equipment for use in aspiration and wound care**

Device Classification:
**IIa**

Device Descriptions:
**Medical suction devices with accessories**

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11491738, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC. Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachments listing model numbers.**

| | | | |
|---|---|---|---|
| File Number | A28433 | Cycle Start Date | 13 January 2017 |
| Certificate No. | 822.170113 | Effective Date | 13 January 2017 |
| | | Expiry Date | 12 January 2022 |

Authorised by

**Anwen E. Evans**
**Certification Manager**
For and on Behalf of UL International (UK) Ltd

**Notified Body**
**0843**

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

# EC CERTIFICATE

**Attachment 1 of 1**

The products detailed below are covered under the scope of this certificate

| Product Family | Product Sub-Group | Model/Type | Classification | G/UMDN Code |
|---|---|---|---|---|
| Medical Suction Equipment | Aspirators | SIMEX M20, M20D, M30D | IIa | |
| | | SIMEX S20, S20K, S30 | IIa | |
| | | SIMEX M20Plus, M30Plus | IIa | |
| | | SIMEX cuff M, cuff S | IIa | |
| | Wound Care | SIM$^{EX200}$ SIM$^{EX300}$ PRO II PRO III | IIa | |

File Number A28433
Certificate No. 822.170113

Cycle Start Date 13 January 2017
Effective Date 13 January 2017
Expiry Date 12 January 2022

Authorised by

**Anwen E. Evans**
**Certification Manager**
For and on Behalf of UL International (UK) Ltd

**Notified Body**
**0843**

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom