

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60022552 0001

Report No.: 21137970 005

Manufacturer: ASSKEA GmbH
Haßlocher Str. 9
99189 Gebesee
Deutschland

Scope: Design/development, manufacture and final inspection
of medical suction equipment


Replaces Approval, Registration No.: HD 60011810 0001

Date of Expiry: 14.01.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Cologne, 07.05.2009


Dipl.-Ing. U. Frenkert



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60022552 0001
Report No.: 21137970 005


Manufacturer: ASSKEA GmbH
Haßlocher Str. 9
99189 Gebesee
Deutschland

Scope: Products:

- ASSKEA AC-series
- ASSKEA DC-series
- ASSKEA M-series
- ASSKEA Pro-series
- ASSKEA S-series
- ASSKEA FIDATO-S
- ASSKEA paediatric suction units
- ASSKEA HEIMO-VAC

Cologne, 07.05.2009

Certification Body


Dipl.-Ing. U. Frenkert

