EC Certificate

TÜVRheinland®

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

Registration No.: HD 1626305-1

Manufacturer: Kröber Medizintechnik GmbH
Salzheck 4
56332 Dieblich
Germany

Products: Medical devices for respiratory therapy

Products included:

Oxygen concentrators:
- Kröber O2
- Kröber O2-p
- Kröber O2 Vers. 4.0
- aeroplus E
- Kröber O2-F
- OxyLink
- OxyLink 10

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.

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TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

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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.