

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

Registration No.: HD 60128027 0001

Report No.: 21247325 009

Manufacturer: Wöhlk Contactlinsen GmbH
Bürgermeister-Schade-Str. 12-16
24232 Schönkirchen
Deutschland

Products: Contact lenses and contact lens care products
Replaces Certificate, Registration No.: HD 60101545 0001

Expiry Date: 2023-06-16

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: 2018-06-17

Date: 2018-04-04

Notified Body


Dr. K. Kluge



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.