

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

Registration No.: HD 60112978 0001

Report No.: 21170866 011

Manufacturer: Amor Gummiwaren GmbH
August-Rost-Str. 4
99310 Arnstadt
Deutschland

Products: - Condoms
- Medical lubricants

(see attachment for sites included)

Replaces Certificate, Registration No.: HD 60091530 0001

Expiry Date: 2021-08-11

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: 2016-08-12

Date: 2016-08-05

Notified Body

Anja Fechner

Dipl.-Ing. A. Fechner



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.