

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60112979 0001

Report No.: 21170866 011

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

Products: Production of medical probe covers
Replaces Certificate, Registration No.: DD 60040485 0001



Expiry Date: 2021-08-11

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2016-08-12

Date: 2016-08-09

Notified Body



Dipl.-Ing. I. Munkler

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.