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TÜVRheinland®

EC Certificate

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

Registration No.: HD 60076790 0001

Report No.: 21182155 002

Manufacturer:
Auto Tissue Berlin GmbH
Goerzallee 305 D
14167 Berlin
Deutschland

Products:

xenogenic pulmonary heart valves
- Matrix P
- Matrix P plus
- Matrix P plus N

equine pericardial patches
- Matrix Patch

Expiry Date: 2017-07-02

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: 2012-07-03

Date: 2012-07-03

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierstelle
Dr. G. Viola

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.