

**EC Design-Examination Certificate**  
**Directive 93/42/EEC Annex II, Section 4**  
**Medical Devices**

**Registration No.:** ID 60124043 0001

**Report No.:** 21182158 005

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

**Product**

**Identification:**

Matrix Patch equine pericardial patches

(see attachment for sizes included)

Replaces Certificate, Registration No.: 60090365 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

**Expiry Date:** 2022-11-15

**Effective Date:** 2017-11-16

**Date:** 2017-11-16

**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** ID 60124043 0001  
**Report No.:** 21182158 007

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

equine pericardial patches, sizes included:

- 2 cm x 2 cm
- 3 cm x 3 cm
- 4 cm x 4 cm
- 5 cm x 5 cm
- 6 cm x 1 cm
- 8 cm x 1 cm
- 8 cm x 2 cm
- 8 cm x 4 cm
- 8 cm x 8 cm
- 10 cm x 2 cm
- 10 cm x 5 cm
- 10 cm x 10 cm

**Date:** 2020-09-10



TÜV Rheinland LGA Products GmbH • 90431 Nuremberg

Auto Tissue Berlin GmbH  
Goerzallee 305d  
14167 Berlin  
Germany

Contact

Phone +49 221 806-4300  
Fax +49 221 806-1601  
Mail [service-med@de.tuv.com](mailto:service-med@de.tuv.com)

Date 2023-05-16

## Status letter

### Conformity Assessment for Matrix Patch

To whom it may concern

Herewith we, TÜV Rheinland LGA Products GmbH (short: TRLP) confirm as Notified Body of the medical device manufacturer Auto Tissue Berlin GmbH, Goerzallee 305 D, 14167 Berlin that the company has applied for a conformity assessment under EU-Regulation 2017/745 (MDR) for the device MatrixPatch-EQ cardiovascular patch under the basic UDI-DI: 4250530604014R.

In January 2023 Auto Tissue Berlin GmbH has been audited according to EU-Regulation 2017/745 Annex IX, Chapter I by TÜV-Rheinland LGA Products GmbH. The CAPA process for the documented nonconformities is ongoing.

The Technical Documentation for the MatrixPatch-EQ cardiovascular patch under the basic UDI-DI: 4250530604014R was provided and the assessment according to EU Regulation 2017/745 Annex IX, Chapter II is ongoing.

Per statement given by the manufacturer Auto Tissue Berlin GmbH the MatrixPatch-EQ cardiovascular patch under EU Regulation 2017/745 is intended to substitute the 'legacy device' Matrix Patch equine pericardial patches under EU-Directive 93/42/EEC (MDD) designed by the manufacturer.

We confirm that the following certificates for the Matrix Patch equine pericardial patches have not been withdrawn prior to the declared date of expiration.

EC Certificate Directive 93/42/EEC, Annex II, excluding Section 4, Full Quality Assurance System Medical Devices, HD 60122669 0001, expired 2022-07-02.

EC Design-Examination Certificate Directive 93/42/EEC, Annex II, Section 4 Medical Devices, ID 60124043 0001, expired 2022-11-15.

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

Phone. +49 911 655 5225  
Fax +49 911 655 5226  
[service@de.tuv.com](mailto:service@de.tuv.com)  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dr. Michael Fübi

- 2 -

As the new product is to be certified under the medical device EU-Regulation 2017/745 (MDR), the MDD certificates were not renewed. TRLP confirms that there is no awareness of any circumstances that would prevent the transition period extension described in EU-Regulation 2023/607 for the previously mentioned certificates (until latest the 31st of December 2027). TRLP will also maintain all required surveillance activities defined in EU-Regulation 2023/607 and a mutual agreement with Auto Tissue Berlin GmbH.

We appreciate your understanding.

Best regards



Certification department

Certification department