EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Stihler Electronic GmbH

Gaussstrasse 4, 70771 Leinfelden-Echterdingen, Germany

Certified location:

Gaussstrasse 4, 70771 Leinfelden-Echterdingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50192-Z6-00, the decision dated 2020-11-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-11-20 to 2023-08-17

Registration No.: 50192-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-11-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50192-16-06

Valid from 2020-11-20 to 2023-08-17

Revision status of the annex: 0 dated 2020-11-20

Devices/device categories included in the certificate:

Class II b:

Patient Warming System

Product name / Product description	REF:
ASTOPAD® Patient Warming System	
ASTOPAD® DUO310 / Control unit (incl. REF 1831.0001, Built-in, rechargeable battery for ASTOPAD DUO310 control unit (optional))	DUO310
ASTOPAD® COV / Heated blanket	COV070 / COV070-2 / COV105 / COV150 / COV155 / COV180
ASTOPAD® SOF / Heated, pressure-relieving OR table cushion	SOF2 / SOF4 / SOF5 / SOF7
ASTOPAD® ROE heated, pressure relieving OR table mattress	ROE4 / ROE8

Warmer for Blood, Intravenous Fluids and Irrigation Fluids

Product name / Product description	REF:
ASTOFLO PLUS ECO	
ASTOFLO PLUS ECO – Control Unit	AFP300EU / AFP300CH / AFP300CN / AFP300DK / AFP300UK / AFP300AU / AFP302EU / AFP302CH / AFP302CN / AFP302DK / AFP302UK / AFP302AU
ASTOFLO PLUS ECO – Heating Profile	WP31 / WP32 / WP33 / WP34
ASTOTHERM® plus	AP200EU / AP200UK / AP220EU / AP220CH / AP220CN / AP220DK / AP220UK / AP220AU / AP220SEU / AP220SCH / AP220SCN / AP220SDK / AP220SUK / AP220SAU / AP260EU / AP260CH / AP260CN / AP260DK / AP260UK / AP260AU / AP260SEU / AP260SCH / AP260SCN / AP260SDK / AP260SUK / AP260SAU
ASTOLINE / Active insulation	AL222 / AL260

Blood Warmer

Product name / Product description	REF:
PRISMAFLO II S - Blood Warmer	
PRISMAFLO II S – Control Unit	PF2300EU / PF2300CN / PF2300UK
PRISMAFLO II S – Heating profile	PF2-WP31 / PF2-WP33
PRISMATHERM II	P2XEU (109820) / P2XUK (109821) / P2XCN (113222)

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15 *

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-11-20
Notified Body ID-number: 0124

DEKRA Certification GmbH – Handwerkstraße 15 – D -70565 Stuttgart

Stihler Electronic GmbH
Mr Jens-Peter Weege
Gaussstrasse 4
70771 Leinfelden-Echterdingen
Germany

DEKRA Certification GmbH
Handwerkstraße 15
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Headquarters
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Date 2024-03-25

Subject: Notified Body Confirmation Letter

Our reference: 50192-CoL-01, Rev. 0

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Weege

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Stihler Electronic GmbH
Gaussstrasse 4
70771 Leinfelden-Echterdingen
Deutschland

SRN Number: DE-MF-000006188

The devices covered by the formal application and the written agreement mentioned above are identified in the Table provided in the Annex. This table identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment

procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Digitally signed by Stephanie Donner
Date: 2024-03-25 08:53:12+01:00

Stephanie Donner
2024-03-25

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50192-CoL-01, Rev. 0

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
ASTOPAD® Patient Warming system **ASTOPAD® DUO310 Control unit** REF: DUO310 **ASTOPAD® COV Heated Blanket** REF: COV070 / COV070-2 / COV105 / COV150 / COV155 / COV180 **ASTOPAD® SOF Heated, pressure-relieving OR table cushion** REF: SOF2 / SOF4 / SOF5 / SOF7 **ASTOPAD® ROE** **Heated, pressure relieving OR table pad** REF: ROE4 / ROE8	Class IIb excluding Class IIb implantable non-WET	Certificate No. 50192-16-06; dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124
ASTOFLO PLUS ECO Control unit REF: AFP300EU / AFP300CH / AFP300CN / AFP300DK / AFP300UK / AFP300AU / AFP302EU / AFP302CH / AFP302CN / AFP302DK / AFP302UK / AFP302AU Heating profile REF: WP31 / WP32 / WP33	Class IIb excluding Class IIb implantable non-WET	Certificate No. 50192-16-06; dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124
ASTOTHERM® plus REF: AP200EU / AP200UK / AP220EU / AP220CH / AP220CN / AP220DK / AP220UK / AP220AU / AP220SEU / AP220SCH / AP220SCN / AP220SDK / AP220SUK / AP220SAU / AP260EU / AP260CH / AP260CN / AP260DK / AP260UK / AP260AU / AP260SEU / AP260SCH / AP260SCN AP260SDK / AP260SUK / AP260SAU **ASTOLINE / Active insulation** REF: AL222 / AL260	Class IIb excluding Class IIb implantable non-WET	Certificate No. 50192-16-06; dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124
Device 4 **ASTOTUBE®** REF: IFT3050 / IFT30410 / IFT30410CN / IFT30460 / IFT40410	Class IIa	Certificate No. 50192-16-06; dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Stihler Electronic GmbH
Mr Moritz Freimut
Gaussstrasse 4
70771 Leinfelden-Echterdingen
Germany

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Headquarters
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Fax +49.711.7861-2615

Date 2024-02-13

Decision concerning your change notification no. 501952-CN22-03: *Discontinuation of the product (Phase Out) PRISMATHERM II, cl. IIb as of 2022-12-31, article no: P2XEU (109820), P2XUK (109821), P2XCN (113222)*

Decision concerning your change notification 501952-CN23-01: *Discontinuation of the product (Phase Out) PRISMAFLO IIS, cl. IIb as of 2023-08-17; article nos. Control Unit REF: PF2300EU, PF2300CN, PF2300UK; article nos. Heating Profile REF: PF2-WP31, PF2-WP33*

Dear Mr. Freimut

Based on the submitted documents regarding the change notifications it has been decided, that the devices affected by the change are not covered anymore by the scope of the certificate according to the annex II to the Directive 93/42/EEC.

Remarks

Since the start of validity of the Regulation (EU) 2017/745 (MDR) on May 26, 2021, an adaptation of certificates according to Directive 93/42/EEC is no longer possible. Therefore, the existing certificate No. 50192-16-06 cannot be changed. Please keep this decision as an appendix to your certificate.

In accordance with the legal requirements, we will make a corresponding notification to the Deutsche Medizinprodukte-Informations- und Datenbanksystem (DMIDS) about the change/restriction of certificate.

Kind regards

DEKRA Certification GmbH

Joachim Thiel

Enclosures:
Invoice