STIHLER ELECTRONIC

Hersteller Konformitätserklärung
Manufacturer Declaration of Conformity

Klasse IIb der Richtlinie 93/42/EWG
Class IIb following MDD 93/42/EEC

Patientenwärmesystem ASTOPAD® bestehend aus:
Patient Warming System ASTOPAD® consisting of:

Produktname / Produktbeschreibung ***Product name / Product description***	**REF:**
ASTOPAD® DUO310 / Steuergerät (inkl. REF 1831.0001, Integrierbare, aufladbare Batterie für ASTOPAD DUO310 Steuergerät (optional)) ***ASTOPAD® DUO310 / Control unit*** *(incl. REF 1831.0001, Built-in, rechargeable battery for ASTOPAD DUO310 control unit (optional))*	DUO310
ASTOPAD® COV / Heizdecke ***ASTOPAD® COV / Heated blanket***	COV070 / COV070-2 / COV105 / COV150 / COV155 / COV180
ASTOPAD® SOF / Beheiztes, druckentlastendes OP-Tischpolster ***ASTOPAD® SOF / Heated, pressure-relieving OR table cushion***	SOF2 / SOF4 / SOF5 / SOF7
ASTOPAD® ROE beheizte, druckentlastende OP-Tischmatratze ***ASTOPAD® ROE heated, pressure relieving OR table mattress***	ROE4 / ROE8

Die Firma STIHLER ELECTRONIC GmbH, Leinfelden-Echterdingen erklärt in alleiniger Verantwortung, dass diese Produkte mit der EG-Richtlinie 93/42/EWG über Medizinprodukte und allen anwendbaren Anforderungen übereinstimmt und das Verfahren nach Anhang II ohne Abschnitt (4) eingehalten wurde.
STIHLER ELECTRONIC GmbH Leinfelden-Echterdingen takes sole responsibility for declaring that these products comply with EC Council Directive 93/42/EEC pertaining to medical products and are consistent with all applicable requirements and has complied with the procedure referred to in Annex II excluding section (4).

Benannte Stelle:
DEKRA Certification GmbH, Handwerkstraße 15, 70565 Stuttgart, Germany
Zulassungsnummer 0124; EG Zertifikat 50192-16-06 gültig von 2020-11-20 bis 2023-08-17
Notified Body:
DEKRA Certification GmbH, Handwerkstraße 15, 70565 Stuttgart, Germany
Identification number 0124; EC Certificate 50192-16-06 valid from 2020-11-20 until 2023-08-17

CE 0124

STIHLER ELECTRONIC GMBH

Michael Schelling
-Managing Director-

Leinfelden-Echterdingen, 2020-12-03
Gültig von 2020-12-03 bis 2023-08-17
Valid from 2020-12-03 until 2023-08-17
APS_SYS_10_09_03_02, Rev. 10

Anschrift / Address
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Germany

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Eingetragen beim Amtsgericht Stuttgart HRB 11674
Stihler Electronic - Medizinische Geräte Produktions- und Vertriebs-GmbH
Vat-ID-Nr. : DE 14786170
Geschäftsführer
Matteo Anversa, Michael Schelling, Dipl.-Ing. Axel Stihler

STIHLERELECTRONIC
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Annex to
Manufacturer Declaration of Conformity APS_SYS_10_09_03_02, rev. 10

Class IIb following MDD 93/42/EEC

Patient Warming System ASTOPAD®

consisting of:

Product name / Product description	REF:
ASTOPAD® DUO310 / Control unit (Incl. REF 1831.0002, Built-in, rechargeable battery for ASTOPAD control unit)	**DUO310**
ASTOPAD® COV / Heating 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**

STIHLER ELECTRONIC GmbH Leinfelden-Echterdingen takes sole responsibility for declaring that these products comply with EC Council Directive 93/42/EEC pertaining to medical products and are consistent with all applicable requirements and have complied with the procedure referred to in Annex II excluding section (4).

Notified Body:	**DEKRA Certification GmbH Handwerkstraße 15 70565 Stuttgart, Germany**
Identification number:	**0124**
EC Certificate:	**50192-16-06** **VALID FROM 2020-11-20 UNTIL 2023-08-17**
Notified Body Confirmation Letter on extension of EC Certificate 50192-16-06:	**50192-CL-00, Rev. 0** **VALID UNTIL THE LATEST: 2024-05-25**
CE marking:	CE 0124

STIHLER ELECTRONIC GMBH

Felix Stihler
-Managing Director-

Leinfelden-Echterdingen, 2023-08-09
Valid from 2023-08-18 until 2024-05-25
Dok-ID: APS_SYS_10_09_03_02a, rev. 02

DEKRA Certification GmbH – Handwerkstraße 15 – D -70565 Stuttgart

Stihler Electronic GmbH
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Date 2023-07-31

Subject: Notified Body Confirmation Letter

Our reference: 50192-CL-00, 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, hereby confirms that a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer is still pending:

Stihler Electronic GmbH
Gaussstrasse 4
70771 Leinfelden-Echterdingen
Deutschland

SRN Number: DE-MF-000006188

Furthermore, DEKRA Certification GmbH confirms that an agreement between Stihler Electronic GmbH and DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the certificate(s) mentioned in table 1 according to Regulation (EU) 2017/745 Article 120.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies, as DEKRA Certification GmbH, in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not

been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate, see Table 1 under certain conditions. Additionally, should the Stihler Electronic GmbH intend to make use of the extension of the validity of the EC-certificates, involvement of DEKRA Certification GmbH for continued surveillance is required.

This Confirmation Letter identifies the products or product groups and EC certificates according to MDD 93/42/EEC (see Table 1) for which Stihler Electronic GmbH intends to make use of the option for extension of the validity of the EC certificates (see Table 1).

This Confirmation Letter identifies its validity until the latest: **2024-05-25**.

If Stihler Electronic GmbH has intentions to make use of the option for extension of the validity of the EC certificates (see Table 1) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607:

- 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)

the following conditions have to be met:

- Stihler Electronic GmbH or it's the Authorized Representative has to ensure that a formal application acc. to the MDR 2017/745 Section 4.3, first subparagraph of Annex VII for the conformity assessment will have been lodged with DEKRA Certification GmbH, latest by 26 May 2024. The application should be placed for the product(s) or groups of products intended to substitute those product(s).
- Stihler Electronic GmbH or its Authorized Representative has to ensure that a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the MDR application not be lodged and the written agreement not to be signed acc. to the mentioned timelines, the EC certificates mentioned in the Table 1, cannot be considered valid after 26. September 2024.

On behalf of the Notified Body,

Stephanie Donner
2023/07/31

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 / COV235 **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	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	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	Certificate: No. 50192-16-06, dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124
ASTOTUBE® REF: IFT3050 / IFT30410 / IFT30410CN / IFT30460 / IFT40410	Class IIa	Certificate: No. 50192-17-08, dated 2020-11-20 Annex revision 0, dated 2020-11-20 NB 0124