# STIHLER ELECTRONIC

## Hersteller Konformitätserklärung
## *Manufacturer Declaration of Conformity*

### Klasse IIa der Richtlinie 93/42/EWG
### *Class IIa following MDD 93/42/EEC*

**Infusionsverlängerung** **ASTOTUBE**
***Infusion extension***

| **Produktname / Produktbeschreibung**<br>***Product name / Product description*** | **REF:** |
|---|---|
| **ASTOTUBE** | IFT30350 / IFT30460 / IFT30410 / IFT30410CN / IFT40410 |

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 VII in Verbindung mit Anhang V 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 Annex VII in combination with Annex V.*

Benannte Stelle:
DEKRA Certification GmbH, Handwerkstraße 15, 70565 Stuttgart, Germany
Zulassungsnummer 0124; EG Zertifikat 50192-17-08 gültig von 2020-11-20 bis 2023-08-17
*Notified Body:*
*DEKRA Certification GmbH, Handwerkstraße 15, 70565 Stuttgart, Germany*
*Identification number 0124; EC Certificate 50192-17-08 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*
*TD_03_07, Rev. 11*

**Anschrift / Address**
Stihler Electronic GmbH
Gaussstrasse 4
70771 Leinfelden-Echterdingen
Germany

**Telefon / Phone :** +49 (0)711-72067-0
**Fax :** +49 (0)711-72067-57
**Internet :** www.stihlerelectronic.de
**e-mail :** info@stihlerelectronic.de

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

STIHLERELECTRONIC
A GENTHERM Company

Technology to the next degree™

Tel. +49 (0) 711-72067 0
Fax. +49 (0) 711-72067 57
E-Mail: info.ste@gentherm.com
www.stihlerelectronic.de

# Annex to Manufacturer Declaration of Conformity TD_03_07, rev. 11

**Class IIa following MDD 93/42/EEC**

**Infusion extension ASTOTUBE®**

| Product name / Product description | REF: |
|---|---|
| ASTOTUBE® | IFT30350 / IFT30460 / IFT30410 / IFT30410CN / IFT40410 |

**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 V.**

| | |
|---|---|
| Notified Body: | DEKRA Certification GmbH<br>Handwerkstraße 15<br>70565 Stuttgart<br>Germany |
| Identification number: | 0124 |
| EC Certificate for the Quality Assurance System: | 50192-17-08<br>VALID FROM 2020-11-20 UNTIL 2023-08-17 |
| Notified Body Confirmation Letter on extension of EC Certificate 50192-17-08: | 50192-CoL-01, Rev. 0<br>VALID UNTIL THE LATEST: 2028-12-31 |
| CE marking: | CE 0124 |

**STIHLER ELECTRONIC GMBH**

**Felix Stihler**
**-Managing Director-**

**Leinfelden-Echterdingen, 2024-02-26**
**Valid from 2024-03-26 until 2028-12-31**

***Dok-ID: TD_03_07a, rev. 03***

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
D -70565 Stuttgart

Contact Karin Heckel
Phone +49.711.7861-3427
Fax +49.711.7861-2615
Email karin.heckel@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

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**<br>**ASTOPAD® DUO310 Control unit**<br>REF: DUO310<br>**ASTOPAD® COV Heated Blanket**<br>REF: COV070 / COV070-2 / COV105 / COV150 / COV155 / COV180<br>**ASTOPAD® SOF Heated, pressure-relieving OR table cushion**<br>REF: SOF2 / SOF4 / SOF5 / SOF7<br>**ASTOPAD® ROE**<br>**Heated, pressure relieving OR table pad**<br>REF: ROE4 / ROE8 | Class IIb excluding Class IIb implantable non-WET | Certificate No. 50192-16-06; dated 2020-11-20<br>Annex revision 0, dated 2020-11-20<br>NB 0124 |
| **ASTOFLO PLUS ECO Control unit**<br>REF:<br>AFP300EU / AFP300CH / AFP300CN / AFP300DK / AFP300UK / AFP300AU /<br>AFP302EU / AFP302CH / AFP302CN / AFP302DK / AFP302UK / AFP302AU<br>Heating profile<br>REF: WP31 / WP32 / WP33 | Class IIb excluding Class IIb implantable non-WET | Certificate No. 50192-16-06; dated 2020-11-20<br>Annex revision 0, dated 2020-11-20<br>NB 0124 |
| **ASTOTHERM® plus**<br>REF:<br>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<br>**ASTOLINE / Active insulation**<br>REF: AL222 / AL260 | Class IIb excluding Class IIb implantable non-WET | Certificate No. 50192-16-06; dated 2020-11-20<br>Annex revision 0, dated 2020-11-20<br>NB 0124 |
| **Device 4**<br>**ASTOTUBE®**<br>REF: IFT3050 / IFT30410 / IFT30410CN / IFT30460 / IFT40410 | Class IIa | Certificate No. 50192-16-06; dated 2020-11-20<br>Annex revision 0, dated 2020-11-20<br>NB 0124 |