

# Sancare Health Co., Ltd

## DECLARATION OF CONFORMITY

We, Sancare Health Co., Ltd. (Manufacturer's Name)

No.38, Ln. 221, Renhua Rd., Dali Dist., Taichung City 412, Taiwan (address)

Declare under our sole responsibility that the product:

- Pulsatile Nasal Irrigator (Class IIa)
- Pulsatile Ear Irrigator (Class IIa)
  - pump system
  - water container and its lid
  - mushroom valve
  - spiral diaphragm
  - motor
  - footswitch
  - panel overlay
  - lid of storage box
  - electronic system
  - replacement ear tips
  - ear canal wicks

To which this declaration relates is in conformity with the following standard(s) or other normative documents(s):

EN ISO 15223-1:2016, EN 1041:2008, EN 60601-1:2006, EN 60601-1-2:2015,  
EN 60601-1-6:2010, EN 60601-1-11:2010, EN ISO 14971:2012, EN ISO 10993-1:2009,  
EN ISO 10993-5:2009, EN ISO 10993-10:2009, EN ISO 13485:2016, EN 62304:2006,  
and EN 62366:2008

(title and/or number and date of issue of the standard(s) or other normative document(s))

(if applicable)

following the provision of Directive:

93/42/EEC and its amendment 2007/47/EC Annex II excluding sec.4

EC Certificate: F116/07016

UK & EU Authorized Representative:

Albert Waeschle Ltd. (name)

11 Balena Close Poole, Dorset, UK BH17 7DB (UK address)

20 Harcourt Street, Dublin 2, Ireland (EU address)

Notified Body (NB):

SGS (0598), SGS Fimko Ltd., Särkiniementie 3, FI-00211 Helsinki, Finland

Taiwan, 2021/07/22

(place and date of issue)

Jimmy Tseng

(Name and signature of equivalent marking of authorized person)



**Von:** [John Hall](#)  
**An:** [Anne Gabriel](#)  
**Betreff:** RE: Declaration of conformity, CE-certificate, confirmation letter for Projet ear tips 190.60.100 (I5 19061)  
**Datum:** Dienstag, 18. März 2025 09:01:25  
**Anlagen:** [image008.png](#)  
[image009.png](#)  
[image010.png](#)  
[image011.png](#)  
[image012.png](#)

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Dear Anne

The confirmation letter from the Medicines and Healthcare products Regulatory Agency allows the certification to be extended until 31<sup>st</sup> December 2027. This allows us to continue to sell the product whilst we secure ISO13485 and create the MDR Technical files. We are currently partnering with a regulatory consultant to put both in place and aim to successfully achieve this by the end of this year or first quarter of 2026.

As soon as we have appointed our Notified Body we will secure a letter to confirm we have entered the process of transition and audit.

Best Regards

John

**John Hall PG Dip DigM**

Group Marketing & Compliance Manager  
ALBERT WAESCHLE Group

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Zumax Website: [www.zumax.co.uk](http://www.zumax.co.uk)

UK Office: Unit 11 Balena Close, Creekmoor Industrial Estate, Poole, Dorset BH17 7DB

EU Office: 20 Harcourt Street, Dublin 2, Ireland



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**From:** Anne Gabriel <anne.gabriel@servoprax.de>

**Sent:** 18 March 2025 07:43

**To:** John Hall <john@albertwaeschle.com>

**Subject:** Declaration of conformity, CE-certificate, confirmation letter for Projet ear tips 190.60.100 (I5 19061)

Dear John,

see the attached documents , please.  
These documents do not comply with the MDR.

If you don ´t have a declaration of conformity and ce-certificate that comply with the MDR you need an extension letter (confirmation letter) from you notified body.

Will you send the DoC/CE-certificate that comply with the MDR or this confirmation letter of your notified body to me, please

Mit freundlichen Grüßen / with kind regards

**Anne Gabriel**  
Qualitätsmanagement

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Geschäftsführer: Michael Benninghoff, Alexander Bungert

**WICHTIGE INFORMATION:**  
**Umstellung unseres Lagerverwaltungssystems vom 19. bis 23. März 2025**  
Die servoprax GmbH modernisiert ihre Logistik mit einem neuen Lagerverwaltungssystem. **Kurzfristige Lieferverzögerungen sind möglich.**  
Danke für Ihr Verständnis – künftig noch besserer Service!

**IMPORTANT INFORMATION:**  
**Changeover of our warehouse management system from March 19 to 23, 2025**  
servoprax GmbH is modernizing its logistics with a new warehouse management system. **Short-term delivery delays are possible.**  
Thank you for your understanding - even better service in the future!

**MEHR INFOS SEE MORE**

**servoprax**<sup>®</sup>