

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 760129 R000

**Manufacturer:** Starkey Labs, Inc.

**Address:**

6700 Washington Avenue South  
Eden Prairie  
Minnesota  
55344  
USA

**Single Registration Number:** US-MF-000014382

**EU Authorised Representative:** Starkey Laboratories (Germany) G.m.b.H

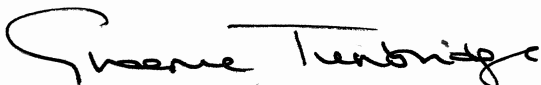
**Address:**

Weg beim Jäger 218-222  
22335 Hamburg  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-08-29**

Current Issue Date: **2023-08-29**

Starting Validity Date: **2023-08-29**

Expiry Date: **2028-08-28**

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Hearing Aids	Class IIa
Hearing Aid Software	Class IIa



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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3560851	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.