MED-EL

EU DECLARATION OF CONFORMITY

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a
6020 Innsbruck, Austria
SRN: AT-MF-000020243

as manufacturer, declares under its sole responsibility that the following product(s) is/are in conformity with the provisions of Regulation (EU) 2017/745 (MDR).

Product Name(s):	SONNET 3 Me1710, Me1711, Me1712, Me1713 (each in colors Anthracite, Beige, Black, Ebony, White and Nordic Grey) SONNET 3 EAS Me1720, Me1721, Me1722, Me1723 (each in colors Anthracite, Beige, Black, Ebony, White and Nordic Grey)
Basic UDI-DI:	9008737Me17xx7N
Intended Purpose:	Audio processor for MED-EL cochlear implant and auditory brainstem implant systems used to evoke auditory sensation
Risk Class in accordance with the rules set out in ANNEX VIII:	Class III
Common Specifications applied:	N/A
Other Union legislation (where applicable):	Directive 2014/53/EU (RED)
Notified Body Name:	TÜV SÜD Product Service GmbH
Notified Body Identification Number:	0123
Conformity Assessment Procedure applied:	☒ Annex IX chapters I – III ☐ Annex IX excluding chapter II ☐ Annex IX excluding chapter II (limited to aspects of sterility/measuring function/reuse of surgical instruments) ☐ Self-declaration
Certificate(s) issued:	G70 017853 0171 Rev. 00

Signed for and on behalf of MED-EL Elektromedizinische Geräte GmbH:

Innsbruck, 2024-09-09

Dr. Ingeborg Hochmair
Chief Executive Officer

Elizabeth Gfoeller
Corporate Director, Regulatory Affairs

Dr. Martin Herzog
Corporate Director, Quality Assurance