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## EC DECLARATION OF CONFORMITY

(Manufacturers Declaration)

**Manufacturer:** Oticon Medical AB  
 Datavägen 37 B  
 SE-436 32 Askim  
 Sweden  
 Telephone: +46 317 486 100  
 Fax: +46 316 877 56  
 SRN: SE-MF-000000724

The Manufacturer hereby declares under its sole responsibility that the devices specified below are in conformity with the requirements of the following Union legislations as amended and implemented in the Member States where the devices are sold:

Document No.	Title	Edition
2017/745/EU [MDR]	Regulation (EU) 2017/45 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	24. Apr. 2020
2014/53/EU [RED]	Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC	9. Nov. 2018
1999/519/EC	Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)	12 Jul. 1999
2011/65/EU [ROHS]	Directive 2011/65/EU of the European parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	1 May 2020

**Device identification:** See Appendix I

**Classification:** Class IIa (as per rule 9 of Annex VIII of Regulation (EU) 2017/745)

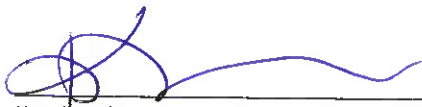
The chosen route to CE marking is conforming to:

- Conformity is assessed according to Regulation (EU) No 2017/745, Article 52 following Annex IX with applicable sections. The manufacturer has established a full quality assurance system corresponding to EN ISO 13485:2016, supported by EU Quality Management System Certificate (MDR) No. G10 106872 003 (and related product lists), issued by TÜV SÜD Product Service GmbH Zertifizierstellen, Ridlerstraße 65, 80339 München, Germany, Notified Body No. 0123.
- Conformity is assessed according to Directive 2014/53/EU, Article 17 - §2(c), following Annex IV – Conformity based on full quality assurance.
- Conformity is assessed according to Directive 2011/65/EU, Article 7.

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The following Common Specification(s) are used to declare this conformity: Not applicable

Signed in Askim 2022-03-31 on behalf of Oticon Medical AB



Karolin Isberg Jernby, Person Responsible for Regulatory Compliance

This Declaration of Conformity is valid until replaced by a new revision, but no longer than 2026-07-18. Any modification of the device not authorised by the Manufacturer will invalidate this declaration.

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### Appendix I

This appendix lists the devices object of the present declaration:

Product type	Article name	Article number	Basic UDI-DI	MDR Risk classification	CND-code
Sound processor	Ponto 4, CBE	186777	57121491000182	Ila	Y214599
Sound processor	Ponto 4, TC	186778	57121491000182	Ila	Y214599
Sound processor	Ponto 4, SIL	186779	57121491000182	Ila	Y214599
Sound processor	Ponto 4, STG	186780	57121491000182	Ila	Y214599
Sound processor	Ponto 4, CNB	186781	57121491000182	Ila	Y214599
Sound processor	Ponto 4, DBL	186782	57121491000182	Ila	Y214599
Sound processor	Ponto 4 DEMO, Terracotta	201386	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, SIL	223155	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, CBE	223156	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, TC	223157	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, CNB	223158	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, STG	223159	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini, DBL	223160	57121491000182	Ila	Y214599
Sound processor	Ponto 5 Mini DEMO, Diamond Black	227042	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, SIL	223161	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, CBE	223162	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, TC	223163	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, CNB	223164	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, STG	223165	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER, DBL	223166	57121491000182	Ila	Y214599
Sound processor	PONTO 5 SUPERPOWER DEMO, DIAMOND BLACK	227043	57121491000182	Ila	Y214599