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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Oticon Medical AB

Datavägen 37B, SE-436 32 Askim, Sweden

Product Category:

- Bone conducting hearing aids and implants for rehabilitation of hearing including accessories and instruments

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41315807-02

Initial Certification Date:
June 3, 2008

Certificate Valid from:
June 4, 2018

Certificate Expiry Date:
June 3, 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

June 1, 2018
Signed Date

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medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

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MDD – Product List

Products included in the Certificate No: 41315807-02
Issued to: **Oticon Medical AB**
Datavägen 37B
SE-436 32 Askim
Sweden

Product category	Type/Model Designation	Class	Sterile	GMDN code (not mandatory)	Date added
Implants					
	Wide implant, 4mm, with abutment, 6mm / M51136	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 4mm, with abutment, 9mm / M51137	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 4mm, with abutment, 12mm / M51138	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 4 mm, with abutment, 14 mm / M52065	IIb	Yes	46638	May 16, 2014
	Wide implant, 4mm / M51139	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 3 mm, with abutment, 6mm / M51140	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 3mm, with abutment, 9mm / M51141	IIb	Yes	46638	Sep 30, 2011
	Wide implant, 3mm / M51142	IIb	Yes	46638	Sep 30, 2011
	Abutment, 6 mm / M50349	IIb	Yes	46638	*
	Abutment, 9 mm / M50318	IIb	Yes	46638	*
	Abutment, 12 mm / M51149	IIb	Yes	46638	Nov 21, 2011
	Abutment, 14 mm / M52063	IIb	Yes	46638	May 16, 2014
	Cover screw hexagon / M50098	IIb	Yes	46638	*
	Soft healing cap / M52080	I	Yes	13369	Oct 21, 2014
	Healing cap / M50821	I	Yes	13369	Oct 8, 2010
	Ponto BHX Implant, 3 mm / M52172	IIb	Yes	46638	May 22, 2015
	Ponto BHX Implant, 4 mm / M52173	IIb	Yes	46638	May 22, 2015
	Ponto BHX Implant, 3 mm, with abutment, 6 mm / M52166	IIb	Yes	46638	May 22, 2015
	Ponto BHX Implant, 3 mm, with abutment, 9 mm / M52167	IIb	Yes	46638	May 22, 2015
	Ponto BHX Implant, 4 mm, with abutment, 6 mm / M52168	IIb	Yes	46638	May 22, 2015
	Ponto BHX Implant, 4 mm, with abutment, 9 mm / M52169	IIb	Yes	46638	May 22 2015
	Ponto BHX Implant, 4 mm, with abutment, 12 mm / M52170	IIb	Yes	46638	May 22, 2015

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Product category	Type/Model Designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Ponto BHX Implant, 4 mm, with abutment, 14 mm / M52171	IIb	Yes	46638	May 22, 2015
Sound processors					
	Ponto 3, L, DBL / M52620	IIa	No	34180	June 17, 2016
	Ponto 3, R, DBL / M52621	IIa	No	34180	June 17, 2016
	Ponto 3, L, MBR / M52622	IIa	No	34180	June 17, 2016
	Ponto 3, R, MBR / M52623	IIa	No	34180	June 17, 2016
	Ponto 3, L, CBE / M52624	IIa	No	34180	June 17, 2016
	Ponto 3, R, CBE / M52625	IIa	No	34180	June 17, 2016
	Ponto 3, L, WHS / M52626	IIa	No	34180	June 17, 2016
	Ponto 3, R, WHS / M52627	IIa	No	34180	June 17, 2016
	Ponto 3, L, STG / M52628	IIa	No	34180	June 17, 2016
	Ponto 3, R, STG / M52629	IIa	No	34180	June 17, 2016
	Ponto 3, L, PUW / M52630	IIa	No	34180	June 17, 2016
	Ponto 3, R, PUW / M52631	IIa	No	34180	June 17, 2016
	Ponto 3 Demo, L, CBE / M52632	IIa	No	34180	June 17, 2016
	Ponto 3 Demo, R, CBE / M52633	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, DBL / M52634	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, DBL / M52635	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, MBR / M52636	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, MBR / M52637	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, CBR / M52638	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, CBR / M52639	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, WHS / M52640	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, WHS / M52641	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, STG / M52642	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, STG / M52643	IIa	No	34180	June 17, 2016
	Ponto 3 Power, L, PUW / M52644	IIa	No	34180	June 17, 2016
	Ponto 3 Power, R, PUW / M52645	IIa	No	34180	June 17, 2016

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MDD – Product List

Product category	Type/Model Designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Ponto 3 SuperPower, L, DBL / M52648	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, DBL / M52649	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, L, MBR / M52650	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, MBR / M52651	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, L, CBR / M52652	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, CBR / M52653	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, L, WHS / M52654	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, WHS / M52655	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, L, STG / M52656	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, STG / M52657	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, L, PUW / M52658	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower, R, PUW / M52659	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower Demo, L, CBR / M52660	IIa	No	34180	June 17, 2016
	Ponto 3 SuperPower Demo, R, CBR / M52661	IIa	No	34180	June 17, 2016
	Ponto 4 CBE 186777	IIa	No	34180	Mar 14, 2019
	Ponto 4 TC 186778	IIa	No	34180	Mar 14, 2019
	Ponto 4 SIL 186779	IIa	No	34180	Mar 14, 2019
	Ponto 4 STG 186780	IIa	No	34180	Mar 14, 2019
	Ponto 4 CNB 186781	IIa	No	34180	Mar 14, 2019
	Ponto 4 DBL 186782	IIa	No	34180	Mar 14, 2019
	Ponto 4 Demo Terracotta 201386	IIa	No	34180	Mar 18, 2019

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Product category	Type/Model Designation	Class	Sterile	GMDN code (not mandatory)	Date added
Fitting software					
	Genie Medical 2016.1 (M50504)	IIa	No	60211	June 17, 2016
	Genie Medical BAHS sales pack 2019.1 UK 197603 USB 197965 DVD	IIa	No	60211	Mar 14, 2019
Accessories and instruments					
	Guide drill, 3-4 mm / M50287	IIa	Yes	47563	*
	Wide countersink, 4mm / M51122	IIa	Yes	47563	April 27, 2012
	Wide countersink, 3mm / M51144	IIa	Yes	47563	Sep 30, 2011
	Handle with screwdriver / M50437	IIa	No	33968	Jan 11, 2010
	Screwdriver, machine / M50384	IIa	No	33968	Jan 11, 2010
	Square fit connection, machine / M50386	IIa	No	33968	Jan 11, 2010
	Abutment inserter,machine / M51695	IIa	No	33968	July 8, 2013
	Ruler / M52143	Im	No	44796	May 16, 2014
	MIPS Surgery Kit, 4 mm / 192232	IIa	Yes	44069	Aug 29, 2018
	MIPS Back-Up Kit, 3 mm / 192233	IIa	Yes	44069	Aug 29, 2018
	MONO Surgery Kit / 220701	IIa	Yes	44069	Jul 02, 2020

* Product added before November 25, 2009

Date of issue: 02 July 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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