

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer: Oticon A/S
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The Manufacturer hereby declares that the hearing instruments:

Product Name:

OPN S

OPN S 1 BTE models: BTE PP 13 2.4G 105, MINIRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G, MINIRITE R LI-ION 2.4G
OPN S 2 BTE models: BTE PP 13 2.4G 105, MINIRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G, MINIRITE R LI-ION 2.4G
OPN S 3 BTE models: BTE PP 13 2.4G 105, MINIRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G, MINIRITE R LI-ION 2.4G

OPN PLAY

OPN Play 1 BTE models: BTE PP 13 2.4G 105, BTE PP 13 2.4G 105 TAR, MINIRITE 312 2.4G, MINIRITE T 312 2.4G, MINIRITE R LI-ION 2.4G
OPN Play 2 BTE models: BTE PP 13 2.4G 105, BTE PP 13 2.4G 105 TAR, MINIRITE 312 2.4G, MINIRITE T 312 2.4G MINIRITE R LI-ION 2.4G

OPN 1

Opn 1 BTE Models: BTE 13 PP 2.4G 105, MRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G
Opn 1 ITE Models: KIT IIC 10 75, KIT IIC 10 85, KIT 10 NFM 75, KIT 10 NFM 75 PB, KIT 10 NFM 85, KIT 10 NFM 85 PB, KIT 10 75, KIT 10 75 PB, KIT 10 85, KIT 10 85 PB, KIT 312 2.4G NFM 85, KIT 312 2.4G NFM 85 PB, KIT 312 NFM 85, KIT 312 NFM 85 PB, KIT 312 2.4G NFM, KIT 312 2.4G NFM PB, KIT 312 NFM, KIT 312 NFM PB, KIT 13 2.4G NFM, KIT 13 NFM

OPN 2

Opn 2 BTE Models: BTE 13 PP 2.4G 105, MRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G
Opn 2 ITE Models: KIT IIC 10 75, KIT IIC 10 85, KIT 10 NFM 75, KIT 10 NFM 75 PB, KIT 10 NFM 85, KIT 10 NFM 85 PB, KIT 10 75, KIT 10 75 PB, KIT 10 85, KIT 10 85 PB, KIT 312 2.4G NFM 85, KIT 312 2.4G NFM 85 PB, KIT 312 NFM 85, KIT 312 NFM 85 PB, KIT 312 2.4G NFM, KIT 312 2.4G NFM PB, KIT 312 NFM, KIT 312 NFM PB, KIT 13 2.4G NFM, KIT 13 NFM

OPN 3

Opn 1 BTE Models: BTE 13 PP 2.4G 105, MRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G
Opn 3 ITE Models: KIT IIC 10 75, KIT IIC 10 85, KIT 10 NFM 75, KIT 10 NFM 75 PB, KIT 10 NFM 85, KIT 10 NFM 85 PB, KIT 10 75, KIT 10 75 PB, KIT 10 85, KIT 10 85 PB, KIT 312 2.4G NFM 85, KIT 312 2.4G NFM 85 PB, KIT 312 NFM 85, KIT 312 NFM 85 PB, KIT 312 2.4G NFM, KIT 312 2.4G NFM PB, KIT 312 NFM, KIT 312 NFM PB, KIT 13 2.4G NFM, KIT 13 NFM

SIYA

Siya 1 BTE Models: BTE 13 2.4G 85, BTE 13 PP 2.4G 105, MRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G
Siya 1 ITE Models: KIT IIC 10 75, KIT IIC 10 85, KIT 10 NFM 75, KIT 10 NFM 75 PB, KIT 10 NFM 85, KIT 10 NFM 85 PB, KIT 10 75, KIT 10 75 PB, KIT 10 85, KIT 10 85 PB, KIT 312 2.4G NFM 85, KIT 312 2.4G NFM 85 PB, KIT 312 NFM 85, KIT 312 NFM 85 PB, KIT 312 2.4G NFM, KIT 312 2.4G NFM PB, KIT 312 NFM, KIT 312 NFM PB, KIT 13 2.4G NFM, KIT 13 NFM

Siya 2 BTE models: BTE 13 2.4G 85, BTE 13 PP 2.4G 105, MRITE 312 2.4G NFM PB, MINIRITE T 312 2.4G
Siya 2 ITE Models: KIT IIC 10 75, KIT IIC 10 85, KIT 10 NFM 75, KIT 10 NFM 75 PB, KIT 10 NFM 85, KIT 10 NFM 85 PB, KIT 10 75, KIT 10 75 PB, KIT 10 85, KIT 10 85 PB, KIT 312 2.4G NFM 85, KIT 312 2.4G NFM 85

PB, KIT 312 NFM 85, KIT 312 NFM 85 PB, KIT 312 2.4G NFM, KIT 312 2.4G NFM PB, KIT 312 NFM, KIT 312 NFM PB, KIT 13 2.4G NFM, KIT 13 NFM

XCEED

XCEED 1 BTE models: BTE SP 13 2.4G 110, BTE UP 675 2.4G 120

XCEED 2 BTE models: BTE SP 13 2.4G 110, BTE UP 675 2.4G 120

XCEED 3 BTE models: BTE SP 13 2.4G 110, BTE UP 675 2.4G 120

XCEED PLAY

XCEED PLAY 1 BTE models: SP 13 2.4G 110, BTE SP 13 2.4G 110 TAR, BTE UP 675 2.4G 120, BTE UP 675 2.4G 120 TAR

XCEED PLAY 2 BTE models: BTE SP 13 2.4G 110, BTE SP 13 2.4G 110 TAR, BTE UP 675 2.4G 120, BTE UP 675 2.4G 120 TAR

DYNAMO

Dynamo SP10 BTE models: BTE 13 WL 110, BTE SP (110)

Dynamo SP 8 BTE models: BTE 13 WL 110, BTE SP (110)

Dynamo SP6 BTE models: BTE 13 WL 110, BTE SP (110)

Dynamo SP4 BTE models: BTE 13 WL 110, BTE SP (110)



SENSEI PRO

Sensei Pro BTE models: BTE 312 75, BRE 13 TAR, BTE 13 90, BTE 13 TAR, SP BTE 13 WL 110, SP BTE 13 WL 110 TAR, RITE 312

SENSEI

Sensei BTE models: Sensei Pro BTE models: BTE 312 75, BRE 13 TAR, BTE 13 90, BTE 13 TAR, SP BTE 13 WL 110, SP BTE 13 WL 110 TAR, RITE 312

GET

Get BTE Models: BTE 13, BTE P 13

Get ITE Models: CIC 10 Kit, CIC P 10 Kit, ITC P Kit, ITC P DIR Kit, ITC P PB Kit, ITCP PB DIR Kit, ITC/ITE Kit, ITC/ITE T Kit

ALTA2 PRO

Alta2 Pro BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIBTE 312 WL 85, DESIGNRITE 10 WL, MINIRITE 312 WL, RITE 312 WL, TI BTE 13 WL 85, TI MINIRITE 312 WL TI RITE 312 WL

Alta2 Pro ITE Models: KIT IIC 10 WL OMNI 75, V2 KIT IIC 10 WL OMNI 75, KIT IIC 10 OMNI 75, RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85 PB, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 13 WL DIR H, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 312 WL OMNI

ALTA2

Alta2 BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIRITE 312 WL, RITE 312 WL

Alta2 ITE Models: RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85, KIT 10 WL OMNI 85 PB, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 312 WL OMNI, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 13 WL DIR H

NERA2 PRO

Nera2 Pro BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIBTE 312 WL 85, DESIGNRITE 10 WL, MINIRITE 312 WL, RITE 312 WL, TI BTE 13 WL 85, TI MINIRITE 312 WL TI RITE 312 WL

Nera2 Pro ITE Models: KIT IIC 10 WL OMNI 75, RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85, KIT 10 WL OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 312 WL OMNI, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 13 WL DIR H, V2 KIT IIC 10 OMNI 75, KIT IIC 10 OMNI 75, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 DIR 85 V, KIT 312 OMNI 85, KIT 13 WL DIR H, KIT 312 DIR V, KIT 312 DIR H, KIT 312 OMNI

NERA2

Nera2 BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIRITE 312 WL, RITE 312 WL
Nera2 ITE Models: RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85, KIT 10 WL OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 312 WL OMNI, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 13 WL DIR H, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 DIR 85 V, KIT 312 OMNI 85, KIT 13 WL DIR H, KIT 312 DIR V, KIT 312 DIR H, KIT 312 OMNI

RIA2 PRO

Ria2 Pro BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIBTE 312 WL 85, DESIGNRITE 10 WL, MINIRITE 312 WL, RITE 312 WL, TI BTE 13 WL 85, TI MINIRITE 312 WLT I RITE 312 WL
Ria2 Pro ITE Models: KIT IIC 10 WL OMNI 75, RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85, KIT 10 WL OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 312 WL OMNI, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 13 WL DIR H, V2 KIT IIC 10 OMNI 75, KIT IIC 10 OMNI 75, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 DIR 85 V, KIT 312 OMNI 85, KIT 13 WL DIR H, KIT 312 DIR V, KIT 312 DIR H, KIT 312 OMNI

RIA2

Ria2 BTE Models: BTE 13 WL 85, BTE 13 WL 100, BTE 13 WL 105, MINIRITE 312 WL, RITE 312 WL
Ria2 ITE Models: RFIT CIC 10 WL OMNI 75, KIT 10 WL OMNI 75, KIT 10 WL OMNI 75 PB, KIT 10 WL OMNI 85, KIT 10 WL OMNI 85 PB, KIT 312 WL DIR 85 V, KIT 312 WL DIR 85 PB V, KIT 13 WL DIR 90 H, KIT 13 WL DIR 90 PB H, KIT 312 WL DIR 90 V, KIT 312 WL DIR 90 PB V, KIT 312 WL OMNI, KIT 312 WL DIR V, KIT 312 WL DIR H, KIT 13 WL DIR H, V2 KIT 10 OMNI 75, V2 KIT 10 OMNI 75 PB, KIT 10 OMNI 75, KIT 10 OMNI 75 PB, KIT 10 OMNI 85, KIT 10 OMNI 85 PB, KIT 312 DIR 85 V, KIT 312 OMNI 85, KIT 13 WL DIR H, KIT 312 DIR V, KIT 312 DIR H, KIT 312 OMNI



Family Name:

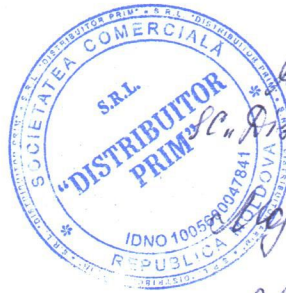
Opn S, Opn Play, Opn 1, Opn 2, Opn 3, Siya, Xceed, Xceed Play, Dynamo, Sensei, Get, Alta 2 Pro, Alta2, Nera 2 Pro, Nera2, Ria2 Pro, Ria2

are classified as medical devices in class IIa and designed and produced in accordance with the requirements of the Council Directive (93/42/EEC as amended) of June 14th 1993 concerning medical devices and its implementation in the countries where the devices are sold.

To fulfill the Council Directive concerning medical devices, the manufacturer has established a full quality assurance system as described in Annex II, excluding section 4, of the Council Directive concerning medical devices – this is supported by the certificate DGM-001 (with the related product list) issued by Presafe Denmark A/S, notified body 0543. The quality system is compliant with DS/EN ISO 13485. Presafe Denmark A/S approves the manufacturer's full quality assurance system - certificate DGM-640.

Signed in Smørum 2019-11-22 on behalf of Oticon A/S


Pernille Parsberg Skydsgaard
Regulatory Affairs Manager



Director
Distributor
Prim S.R.L.
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