

Anexă

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 17 din 06.11.2023

Solicitantul **SC Distribuitor Prim SRL**, cu sediul **Republica Moldova, Chisinau, bl. Dacia 36A**, tel./fax: **022-92-92-62**, e-mail **medtehmd@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. Aparat auditiv Oticon RUBY 2 BTE (Oticon, Danemarca);
2. Aparat auditiv Oticon PG 10 BTE SP (Oticon, Danemarca);

Se anexează următoarele acte:

1. **Certificate de conformitate CE valabil pentru dispozitivele fabricate**
2. **Declaratii de conformitate CE emisa de producator pentru dispozitivul medical fabricat**
3. **Actul prin care producatorul isi desemneaza reprezentantul**

Data 06.11.2023



Semnătura

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr: 8022 din 08.11.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Cerlat Ilarina Gicunginec
Semnătura persoanei responsabile	Cerlat



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 003348 0003 Rev. 00

Manufacturer:

SBO Hearing A/S

Kongebakken 9
2765 Smørum
DENMARK

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10_003348_0003 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_003348_0003_Rev_00)

Report No.:

713173098_Oticon A/S

Valid from:

2020-10-02

Valid until:

2025-08-12

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2020-10-02



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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 003348 0003 Rev. 00

Device Group: Y2145 - HEARING AIDS
Classification: IIa
Intended Purpose: -

The validity of this certificate - none -
depends on conditions and/or
is limited to the following:

<u>EU QMS certificate number</u>	<u>Legal manufacturer</u>	<u>SRN</u>	<u>Product type</u>	<u>Product Brand</u> (private label customer)	<u>Product Family</u> Only applicable for His	<u>Product identification</u> (Medical Device Description)	<u>KIT identification</u> only applicable for ITE styles	<u>App operating systems</u> Only applicable for apps; iOS/Andro id	<u>Class EU</u> <u>MDR</u>	<u>Placed on the market</u> Date for signed EU MDR DOC	<u>Basic UDI-DI</u>	<u>CND code</u>	<u>GMDN code</u>	<u>MDA/ MDN code</u>	<u>MDS code</u>
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 1 BTE	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 1 BTE PP	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 1 MINIRITE	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 1 MINIRITE T	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Jet	OTICON JET 1 IIC	JET 1 KIT IIC 10 75 JET 1 KIT IIC 10 85	N/A	Class IIa	2022-08-10	57144640-HI- 00081-RL	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Jet	OTICON JET 1 CIC	JET 1 KIT 10 NFM 85 PB JET 1 KIT 10 NFM 85 JET 1 KIT 10 85 PB JET 1 KIT 10 85 JET 1 KIT 10 NFM 75 PB JET 1 KIT 10 75 PB JET 1 KIT 10 NFM 75 JET 1 KIT 10 75	N/A	Class IIa	2022-08-10	57144640-HI- 00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Jet	OTICON JET 1 ITC	JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM JET 1 KIT 312 NFM 85 PB JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Jet	OTICON JET 1 ITE HS	JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM JET 1 KIT 312 NFM 85 PB JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM JET 1 KIT 13 2.4G NFM JET 1 KIT 13 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Jet	OTICON JET 1 ITE FS	JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM JET 1 KIT 312 NFM 85 PB JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM JET 1 KIT 13 2.4G NFM JET 1 KIT 13 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 2 BTE	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (BTE)	Oticon	Jet	OTICON JET 2 BTE PP	N/A	N/A	Class IIa	2022-08-10	57144640-HI- 000014-WQ	Y2145	34671 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Jet	OTICON JET 2 MINIRITE	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Jet	OTICON JET 2 MINIRITE T	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Jet	OTICON JET 2 IIC	JET 2 KIT IIC 10 85 JET 2 KIT IIC 10 75	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Jet	OTICON JET 2 CIC	JET 2 KIT 10 NFM 75 JET 2 KIT 10 NFM 85 JET 2 KIT 10 NFM 75 PB JET 2 KIT 10 NFM 85 PB JET 2 KIT 10 75 JET 2 KIT 10 85 JET 2 KIT 10 75 PB JET 2 KIT 10 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Jet	OTICON JET 2 ITC	JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM JET 2 KIT 312 NFM 85 PB JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Jet	OTICON JET 2 ITE FS	JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM JET 2 KIT 312 NFM 85 PB JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM JET 2 KIT 13 2.4G NFM JET 2 KIT 13 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Jet	OTICON JET 2 ITE HS	JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM JET 2 KIT 312 NFM 85 PB JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM JET 2 KIT 13 2.4G NFM JET 2 KIT 13 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 1 MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 1 MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 1 MINIRITE R	N/A	N/A	Class IIa	2020-12-16	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 1 MINIRITE T	N/A	N/A	Class IIa	2021-08-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 2 MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 2 MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 2 MINIRITE R	N/A	N/A	Class IIa	2020-12-16	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 2 MINIRITE T	N/A	N/A	Class IIa	2021-08-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 3 MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 3 MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 3 MINIRITE R	N/A	N/A	Class IIa	2020-12-16	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	More	OTICON MORE 3 MINIRITE T	N/A	N/A	Class IIa	2021-08-10	57144640-HI-00052-R8	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 1 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 1 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 1 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 1 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 2 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 2 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 2 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn Play	OTICON OPN PLAY 2 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 1 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 1 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 1 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 1 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 2 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 2 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 2 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 2 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 3 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 3 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 3 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Opn S	OTICON OPN S 3 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Own	OTICON OWN 1 IIC	OWN 1 KIT IIC 10 75 OWN 1 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	Oticon	Own	OTICON OWN 1 CIC	OWN 1, KIT 10 NFM 75 PB OWN 1, KIT 10 NFM 75 OWN 1, KIT 10 NFM 90 PB OWN 1, KIT 10 NFM 90 OWN 1, KIT 10 75 PB OWN 1, KIT 10 75 OWN 1, KIT 10 90 PB OWN 1, KIT 10 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 1 ITC	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 1 ITE HS	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 1 ITE FS	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 2 IIC	OWN 2 KIT IIC 10 75 OWN 2 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 2 CIC	OWN 2, KIT 10 NFM 75 PB OWN 2, KIT 10 NFM 75 OWN 2, KIT 10 NFM 90 PB OWN 2, KIT 10 NFM 90 OWN 2, KIT 10 75 PB OWN 2, KIT 10 75 OWN 2, KIT 10 90 PB OWN 2, KIT 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 2 ITC	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 2 ITE HS	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 2 ITE FS	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 3 IIC	OWN 3 KIT IIC 10 75 OWN 3 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 3 CIC	OWN 3, KIT 10 NFM 90 PB OWN 3, KIT 10 NFM 90 OWN 3, KIT 10 NFM 75 PB OWN 3, KIT 10 NFM 75 OWN 3, KIT 10 90 PB OWN 3, KIT 10 90 OWN 3, KIT 10 75 PB OWN 3, KIT 10 75	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 3 ITC	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM 90 OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM 90 OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 3 ITE HS	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM 90 OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM 90 OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 3 ITE FS	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM 90 OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM 90 OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 4 IIC	OWN 4 KIT IIC 10 75 OWN 4 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 4 CIC	OWN 4, KIT 10 NFM 90 PB OWN 4, KIT 10 NFM 90 OWN 4, KIT 10 NFM 75 PB OWN 4, KIT 10 NFM 75 OWN 4, KIT 10 90 PB OWN 4, KIT 10 90 OWN 4, KIT 10 75 PB OWN 4, KIT 10 75	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 4 ITC	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 4 ITE HS	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 4 ITE FS	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 5 IIC	OWN 5 KIT IIC 10 75 OWN 5 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 5 CIC	OWN 5, KIT 10 NFM 90 PB OWN 5, KIT 10 NFM 90 OWN 5, KIT 10 NFM 75 PB OWN 5, KIT 10 NFM 75 OWN 5, KIT 10 90 PB OWN 5, KIT 10 90 OWN 5, KIT 10 75 PB OWN 5, KIT 10 75	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 5 ITC	OWN 5, KIT 312 2.4G NFM 90 PB OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 2.4G NFM PB OWN 5, KIT 312 2.4G NFM OWN 5, KIT 312 NFM 90 PB OWN 5, KIT 312 NFM 90 OWN 5, KIT 312 NFM PB OWN 5, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	Oticon	Own	OTICON OWN 5 ITE HS	OWN 5, KIT 312 2.4G NFM 90 PB OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 2.4G NFM PB OWN 5, KIT 312 2.4G NFM OWN 5, KIT 312 NFM 90 PB OWN 5, KIT 312 NFM 90 OWN 5, KIT 312 NFM PB OWN 5, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Ruby	OTICON RUBY 2 BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Ruby	OTICON RUBY 2 MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Ruby	OTICON RUBY 2 MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Ruby	OTICON RUBY 2 MINIRITE R	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 1 MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 1 MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 1 MINIRITE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 1 MINIRITE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 2 MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 2 MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 2 MINIRITE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Zircon	OTICON ZIRCON 2 MINIRITE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 1 BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 2 BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 3 BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 1 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 2 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed	OTICON XCEED 3 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed Play	OTICON XCEED PLAY 1 BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed Play	OTICON XCEED PLAY 2 BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed Play	OTICON XCEED PLAY 1 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	Xceed Play	OTICON XCEED PLAY 2 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	CROS/BI-CROS transmitter	Oticon	Cros	OTICON CROS PX MINIRITE R	N/A	N/A	Class IIa	2021-08-10	57144640-CROS-00068-	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	CROS/BI-CROS transmitter	Oticon	Cros	OTICON CROS MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-CROS-00075-	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Fitting Software	Oticon	N/A	OTICON GENIE 2 2022.2	N/A	N/A	Class IIa	2022-08-08	57144640-fSW-000011-25	Y2145	60211	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Fitting Software	Oticon	N/A	OTICON GENIE 2 2023.1	N/A	N/A	Class IIa	2023-02-06	57144640-fSW-000011-25	Y2145	60211	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	OneApp	Oticon	N/A	OTICON COMPANION 1.1.0	N/A	Android + iOS	Class IIa	2023-04-19	iOS: 57144640-ONEAPP-	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Remote Fitting App	Oticon	N/A	OTICON REMOTECARE 3.5.0	N/A	Android + iOS	Class IIa	2022-08-10	iOS: 57144640-RFITAPP-	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Remote Control App	Oticon	N/A	OTICON ON 2.5.0	N/A	Android + iOS	Class IIa	2021-10-12	iOS: 57144640-RCAPP-00005-	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	E	HHM E300 MINIBTE R	N/A	N/A	Class IIa	2023-02-08	57144640-HI-00052-R8	Y2145	3467138049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	E	HHM E300 MINIBTE T	N/A	N/A	Class IIa	2023-02-08	57144640-HI-00052-R8	Y2145	3467138049	0310	1009

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G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F500 CIC	OWN 1, KIT 10 90 PB OWN 1, KIT 10 75 PB OWN 1, KIT 10 NFM 75 PB OWN 1, KIT 10 75 OWN 1, KIT 10 NFM 90 OWN 1, KIT 10 90 OWN 1, KIT 10 NFM 90 PB OWN 1, KIT 10 NFM 75	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F500 ITC	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F500 ITE HS	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F500 ITE FS	OWN 1, KIT 312 2.4G NFM 90 PB OWN 1, KIT 312 2.4G NFM PB OWN 1, KIT 312 2.4G NFM 90 OWN 1, KIT 312 2.4G NFM OWN 1, KIT 312 NFM 90 PB OWN 1, KIT 312 NFM PB OWN 1, KIT 312 NFM 90 OWN 1, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F400 IIC	OWN 2 KIT IIC 10 75 OWN 2 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F400 CIC	OWN 2, KIT 10 75 OWN 2, KIT 10 NFM 90 PB OWN 2, KIT 10 90 OWN 2, KIT 10 NFM 75 PB OWN 2, KIT 10 75 PB OWN 2, KIT 10 90 PB OWN 2, KIT 10 NFM 75 OWN 2, KIT 10 NFM 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F400 ITC	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F400 ITE HS	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F400 ITE FS	OWN 2, KIT 312 2.4G NFM 90 PB OWN 2, KIT 312 2.4G NFM PB OWN 2, KIT 312 2.4G NFM 90 OWN 2, KIT 312 2.4G NFM OWN 2, KIT 312 NFM 90 PB OWN 2, KIT 312 NFM PB OWN 2, KIT 312 NFM 90 OWN 2, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F300 IIC	OWN 3 KIT IIC 10 75 OWN 3 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F300 CIC	OWN 3, KIT 10 NFM 75 OWN 3, KIT 10 90 OWN 3, KIT 10 75 PB OWN 3, KIT 10 90 PB OWN 3, KIT 10 NFM 75 PB OWN 3, KIT 10 NFM 90 PB OWN 3, KIT 10 NFM 90 OWN 3, KIT 10 75	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F300 ITC	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 2.4G NFM 90 OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM OWN 3, KIT 312 NFM 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F300 ITE HS	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 NFM 90 OWN 3, KIT 312 2.4G NFM 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F300 ITE FS	OWN 3, KIT 312 2.4G NFM 90 PB OWN 3, KIT 312 2.4G NFM PB OWN 3, KIT 312 NFM PB OWN 3, KIT 312 NFM 90 PB OWN 3, KIT 312 NFM OWN 3, KIT 312 2.4G NFM OWN 3, KIT 312 NFM 90 OWN 3, KIT 312 2.4G NFM 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F200 IIC	OWN 4 KIT IIC 10 75 OWN 4 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F200 CIC	OWN 4, KIT 10 NFM 75 OWN 4, KIT 10 90 OWN 4, KIT 10 75 OWN 4, KIT 10 NFM 90 PB OWN 4, KIT 10 75 PB OWN 4, KIT 10 90 PB OWN 4, KIT 10 NFM 75 PB OWN 4, KIT 10 NFM 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F200 ITC	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F200 ITE HS	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F200 ITE FS	OWN 4, KIT 312 2.4G NFM 90 PB OWN 4, KIT 312 2.4G NFM PB OWN 4, KIT 312 2.4G NFM 90 OWN 4, KIT 312 2.4G NFM OWN 4, KIT 312 NFM 90 PB OWN 4, KIT 312 NFM PB OWN 4, KIT 312 NFM 90 OWN 4, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F100 IIC	OWN 5 KIT IIC 10 75 OWN 5 KIT IIC 10 90	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F100 CIC	OWN 5, KIT 10 NFM 90 OWN 5, KIT 10 NFM 90 PB OWN 5, KIT 10 75 PB OWN 5, KIT 10 90 PB OWN 5, KIT 10 NFM 75 PB OWN 5, KIT 10 90 OWN 5, KIT 10 75 OWN 5, KIT 10 NFM 75	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF- 000001270	HI (ITE)	HHM	F	HHM F100 ITC	OWN 5, KIT 312 2.4G NFM 90 PB OWN 5, KIT 312 2.4G NFM PB OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 2.4G NFM OWN 5, KIT 312 NFM 90 PB OWN 5, KIT 312 NFM PB OWN 5, KIT 312 NFM 90 OWN 5, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI- 00076-RW	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F100 ITE HS	OWN 5, KIT 312 2.4G NFM 90 PB OWN 5, KIT 312 2.4G NFM PB OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 NFM 90 PB OWN 5, KIT 312 NFM PB OWN 5, KIT 312 NFM 90 OWN 5, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	F	HHM F100 ITE FS	OWN 5, KIT 312 2.4G NFM 90 PB OWN 5, KIT 312 2.4G NFM PB OWN 5, KIT 312 2.4G NFM 90 OWN 5, KIT 312 2.4G NFM OWN 5, KIT 312 NFM 90 PB OWN 5, KIT 312 NFM PB OWN 5, KIT 312 NFM 90 OWN 5, KIT 312 NFM	N/A	Class IIa	2022-08-10	57144640-HI-00076-RW	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F300 C MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F300 C MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HMM F300 C MINIRITE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F300 C MINIRITE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F500 C MINIBTE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F500 C MINIBTE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F500 C MINIRITE R	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	F C	HHM F500 C MINIRITE T	N/A	N/A	Class IIa	2022-02-10	57144640-HI-00052-R8	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G80 BTE	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G80 BTE PP	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G80 MINIRITE	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G80 MINIRITE T	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G80 IIC	JET 1 KIT IIC 10 75 JET 1 KIT IIC 10 85	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G80 CIC	JET 1 KIT 10 NFM 75 JET 1 KIT 10 NFM 75 PB JET 1 KIT 10 NFM 85 JET 1 KIT 10 NFM 85 PB JET 1 KIT 10 75 JET 1 KIT 10 75 PB JET 1 KIT 10 85 JET 1 KIT 10 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G80 ITC	JET 1 KIT 312 2.4G NFM JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 NFM JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G80 ITE HS	JET 1 KIT 312 2.4G NFM JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 NFM JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G80 ITE FS	JET 1 KIT 312 2.4G NFM JET 1 KIT 312 2.4G NFM 85 JET 1 KIT 312 2.4G NFM 85 PB JET 1 KIT 312 2.4G NFM PB JET 1 KIT 312 NFM JET 1 KIT 312 NFM PB JET 1 KIT 312 NFM 85 JET 1 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G60 BTE	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G60 BTE PP	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G60 MINIRITE	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G	HHM G60 MINIRITE T	N/A	N/A	Class IIa	2022-08-10	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G60 IIC	JET 2 KIT IIC 10 85 JET 2 KIT IIC 10 75	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G60 CIC	JET 2 KIT 10 NFM 75 JET 2 KIT 10 NFM 75 PB JET 2 KIT 10 NFM 85 JET 2 KIT 10 NFM 85 PB JET 2 KIT 10 75 JET 2 KIT 10 75 PB JET 2 KIT 10 85 JET 2 KIT 10 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G60 ITC	JET 2 KIT 312 2.4G NFM JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 NFM JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G60 ITE HS	JET 2 KIT 312 2.4G NFM JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 NFM JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (ITE)	HHM	G	HHM G60 ITE FS	JET 2 KIT 312 2.4G NFM JET 2 KIT 312 2.4G NFM 85 JET 2 KIT 312 2.4G NFM 85 PB JET 2 KIT 312 2.4G NFM PB JET 2 KIT 312 NFM JET 2 KIT 312 NFM PB JET 2 KIT 312 NFM 85 JET 2 KIT 312 NFM 85 PB	N/A	Class IIa	2022-08-10	57144640-HI-00081-RL	Y2145	34672 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G S	HHM G500 S BTE PP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	G S	HHM G500 S MINIRITE	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009

[illegible]

EU MDR Product List

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG	HHM PG50 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG	HHM PG30 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG	HHM PG10 BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671 38049	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG C	HHM PG50 C BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG C	HHM PG30 C BTE SP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG C	HHM PG50 C BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	HHM	PG C	HHM PG30 C BTE UP	N/A	N/A	Class IIa	2023-05-04	57144640-HI-000014-WQ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	CROS/BI-CROS transmitter	HHM	CROS Mic	CROS MIC PX MINIRITE R	N/A	N/A	Class IIa	2021-08-10	57144640-CROS-00068-L5	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	CROS/BI-CROS transmitter	HHM	CROS Mic	CROS MIC MINIRITE T	N/A	N/A	Class IIa	2023-05-04	57144640-CROS-00075-KZ	Y2145	34671	0310	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Remote Fitting App	Neutral (HHM)	N/A	REMOTEFIT 3.5.0	N/A	Android + iOS	Class IIa	2022-08-10	iOS: 57144640-RFITAPP-00056-2Q Android: 57144640-RFITAPP-00056-2Q	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	Remote Control App	Neutral	N/A	REMOTELINK 2.5.0	N/A	Android + iOS	Class IIa	2021-10-12	iOS: 57144640-RCAPP-00005-A3 Android: 57144640-RCAPP-00006-A6	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	OneApp	Neutral	N/A	REMOTELINK 2 1.1.0	N/A	Android + iOS	Class IIa	2023-04-19	iOS: 57144640-ONEAPP-00085-KJ Android: 57144640-ONEAPP-00086-KM	Y2145	57885	0315	1009
G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	FW Updater App	Neutral	N/A	FW UPDATER 1.0.1	N/A	iOS	Class IIa	2022-07-08	iOS: 57144640-FWUAPP-00072-ZG	Y2145	57885	0315	1009

Signed on behalf of SBO Hearing A/S

Date: 2023-05-06

PRRC (name): Mette Bang Dyhrberg

Signature:



DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer: SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum
Denmark
Telephone +45 39 17 71 00
Fax +45 39 27 79 00
Single Registration Number (SRN): DK-MF-000001270

This declaration of conformity is issued under the sole responsibility of SBO Hearing A/S.

The Manufacturer hereby declares that the listed medical devices are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

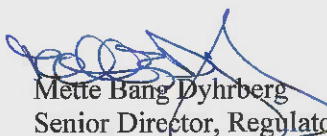
EU Medical Device Regulation (MDR) 2017/745

To fulfil the European requirements concerning medical devices, the manufacturer has established a full quality assurance system as described in Annex IX of the MDR for class IIa devices (excluding not applicable sections) supported by EU certificate G10 003348 0003 (with related product list) issued by the Manufacturer's Notified Body (NB) 0123 TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany

EU Radio Equipment Directive (RED) 2014/53/EU Conformity assessment to Article 3 – Essential Requirements performed by SBO Hearing A/S.

EU RoHS Directive 2011/65/EU and amendment Commission Delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU and applied standard IEC 63000:2016 Conformity assessment to restriction of the use of certain hazardous substances in electrical and electronic equipment directive including all applicable amendments performed by SBO Hearing A/S.

Signed in Smørum 2023-05-04 on behalf of SBO Hearing A/S


Mette Bang Dyhrberg
Senior Director, Regulatory Affairs
Person Responsible for Regulatory Compliance



SBO Hearing A/S

Medical devices covered by this declaration of conformity:

Product identification <i>(Medical Device Description)</i>	Brand	Basic UDI-DI
Oticon Ruby 1 BTE	Oticon	57144640-HI-000014-WQ
Oticon Ruby 2 BTE		
Oticon Ruby 1 BTE PP		
Oticon Ruby 2 BTE PP		
Oticon Ruby 1 miniRITE T		
Oticon Ruby 2 miniRITE T		
Oticon Ruby 1 miniRITE R		
Oticon Ruby 2 miniRITE R		
Oticon Ruby 1 miniRITE		
Oticon Ruby 2 miniRITE		

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer: SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum
Denmark
Telephone +45 39 17 71 00
Fax +45 39 27 79 00
Single Registration Number (SRN): DK-MF-000001270

This declaration of conformity is issued under the sole responsibility of SBO Hearing A/S.

The following Common Specification(s) are used to declare this conformity: N/A

The Manufacturer hereby declares that the listed medical devices are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

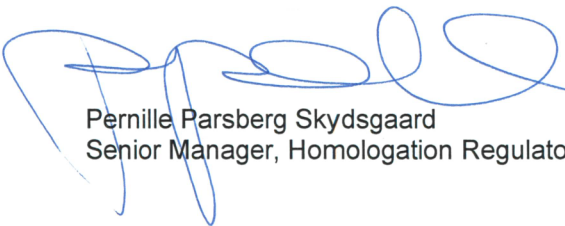
EU Medical Device Regulation (MDR) 2017/745

To fulfil the European requirements concerning medical devices, the manufacturer has established a full quality assurance system as described in Annex IX of the MDR for class IIa devices (excluding not applicable sections) supported by EU certificate G10 003348 0003 (with related product list) issued by the Manufacturer's Notified Body (NB) 0123 TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany

EU Radio Equipment Directive (RED) 2014/53/EU Conformity assessment to Article 3 – Essential Requirements performed by SBO Hearing A/S.

EU RoHS Directive 2011/65/EU and amendment Commission Delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU and applied standard IEC 63000:2016 Conformity assessment to restriction of the use of certain hazardous substances in electrical and electronic equipment directive including all applicable amendments performed by SBO Hearing A/S.

Signed in Smørum 2023-10-06 on behalf of SBO Hearing A/S


Pernille Parsberg Skydsgaard
Senior Manager, Homologation Regulatory Affairs



Medical devices covered by this declaration of conformity:

Product identification <i>(Medical Device Description)</i>	Brand	Basic UDI-DI
Oticon PG50 BTE SP	Oticon	57144640-HI-000014-WQ
Oticon PG30 BTE SP		
Oticon PG10 BTE SP		
Oticon PG50 BTE UP		
Oticon PG30 BTE UP		
Oticon PG10 BTE UP		

To Whom it May Concern

30 March 2023

We, SBO Hearing A/S

Based at Kongebakken 9, DK-2765 Smørum, Denmark

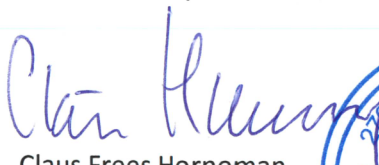
Assign, Distributor Prim SRL

based in 36A Dacia Street, 2060, Kishinev, Moldova

as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Yours Sincerely



Claus Frees Horneman



Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **SC Distribuitor Prim SRL** cu sediul **Chisinau, Bl. Dacia, 36A**

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Certificatul de conformitate CE valabil pentru dispozitivele fabricate;**
2. **Declaratia de conformitate CE emisa de producator pentru dispozitivul medical fabricat;**
3. **Actul prin care producatorul isi desemneaza reprezentantul.**

Sunt autentice și corespund realității.

Director Mojila Violetta



Semnătura

M. Bond

Data

06.11.2023