



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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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 (private label customer)</u>	<u>Product Family Only applicable for His</u>	<u>Product identification (Medical Device Description)</u>	<u>KIT identification only applicable for ITE styles</u>	<u>App. operating systems Only applicable for apps; iOS/Andro id</u>	<u>Class EU MDR</u>	<u>Placed on the market Date for signed EU MDR DOC</u>	<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	Intent	OTICON INTENT 1 MINIRITE	N/A	N/A	Class IIa	2024-02-07	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	Intent	OTICON INTENT 2 MINIRITE	N/A	N/A	Class IIa	2024-02-07	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	Intent	OTICON INTENT 3 MINIRITE	N/A	N/A	Class IIa	2024-02-07	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	Intent	OTICON INTENT 4 MINIRITE	N/A	N/A	Class IIa	2024-02-07	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	Intent	OTICON INTENT DEMOfLEX MINIRITE	N/A	N/A	Class IIa	2024-02-07	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	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

EU MDR Product List

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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

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[illegible]

EU MDR Product List

G10 003348 0003 Rev. 00 (Oticon)	SBO Hearing A/S	DK-MF-000001270	HI (BTE)	Oticon	G	OTICON 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)	Oticon	G	OTICON 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)	Oticon	G	OTICON 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 (BTE)	Oticon	PG	Oticon PG50 BTE SP	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	PG	Oticon PG30 BTE SP	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	PG	Oticon PG10 BTE SP	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	PG	Oticon 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)	Oticon	PG	Oticon 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)	Oticon	PG	Oticon 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	Fitting Software	Oticon	N/A	OTICON GENIE 2 2024.1	N/A	N/A	Class IIa	2024-02-07	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 2024.2	N/A	N/A	Class IIa	2024-08-07	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 1.3.1	N/A	Android + iOS	Class IIa	2024-04-26	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	Remote Control App	Oticon	N/A	OTICON ON 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

Signed on behalf of SBO Hearing A/S

Date: 2024-08-07

PRRC (name): Mette Bang Dyhrberg

Signature:

