



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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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> <i>(private label customer)</i> | <u>Product Family</u> <i>Only applicable for His</i> | <u>Product identification</u> <i>(Medical Device Description)</i> | <u>KIT identification</u> <i>only applicable for ITE styles</i> | <u>App. operating systems</u> <i>Only applicable for apps; iOS/Android</i> | <u>Class EU MDR</u> | <u>Placed on the market</u> <i>Date for signed EU MDR DOC</i> | <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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467138049 | 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 | 3467238049 | 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 | 3467238049 | 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 | 3467238049 | 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 | 3467238049 | 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 | 3467238049 | 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 | 3467138049 | 0310 | 1009 |

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|----------------------------------|-----------------|-----------------|----------|--------|------|--------------------------|---|-----|-----------|------------|-----------------------|-------|----------------|------|------|
| 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 |

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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 |

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|----------------------------------|-----------------|-----------------|----------|--------|-----|---------------------|--|-----|-----------|------------|----------------------|-------|----------------|------|------|
| 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 |

EU MDR Product List

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|----------------------------------|-----------------|-----------------|--------------------|--------|-----|------------------------|-----|---------------|-----------|------------|--|-------|-------------|------|------|
| 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:

