

| EU QMS certificate number          | Legal manufacturer | SRN             | Product type             | Product Brand | Product Family<br>Only applicable<br>for His | Product identification<br>(Medical Device Description) | KIT identification<br>only applicable for ITE styles                                                                                                                                                             | App operating<br>systems<br>Only applicable for<br>apps; iOS/Android | Class EU<br>MDR | Placed on the<br>market<br>Date for signed<br>EU MDR DOC | Basic UDI-DI                                                     | CND code | GMDN<br>code   | MDA/<br>MDN code | MDS code |
|------------------------------------|--------------------|-----------------|--------------------------|---------------|----------------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------|----------------------------------------------------------|------------------------------------------------------------------|----------|----------------|------------------|----------|
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | Fitting Software         | Bernafon      | N/A                                          | Bernafon Oasisnxt 2024.2                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2024.08.07                                               | 57144640-FSW-000012-28                                           | Y2145    | 60211          | 0315             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | Fitting Software         | Bernafon      | N/A                                          | Bernafon Oasisnxt 2025.1                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2025.02.06                                               | 57144640-FSW-000012-28                                           | Y2145    | 60211          | 0315             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | OneApp                   | Bernafon      | N/A                                          | Bernafon App 1.5.2                                     | N/A                                                                                                                                                                                                              | Android + iOS                                                        | Class Ila       | 2025.04.22                                               | Android:57144640-ONEAPP-00088-KT<br>iOS:57144640-ONEAPP-00087-KQ | Y2145    | 57885          | 0315             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 9 MNR T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2020.12.16                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 7 MNR T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2020.12.16                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 5 MNR T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2020.12.16                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 3 MNR T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 1 MNR T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 9 MNR T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2021.08.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 7 MNR T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2021.08.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 5 MNR T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2021.08.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 3 MNR T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 1 MNR T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 9 MNB T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 7 MNB T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 5 MNB T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 3 MNB T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 1 MNB T                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 9 MNB T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 7 MNB T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 5 MNB T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 3 MNB T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Alpha                                        | Bernafon Alpha 1 MNB T R                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.02.10                                               | 57144640-HI-00053-RB                                             | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | CROS/BI-CROS transmitter | Bernafon      | CROS                                         | Bernafon CROS MNR T R                                  | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2021.08.10                                               | 57144640-CROS-00069-L8                                           | Y2145    | 34671          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 2 MNR                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 1 MNR                                 | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 2 MNR T                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 1 MNR T                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 2 B 105                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (BTE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 1 B 105                               | N/A                                                                                                                                                                                                              | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-000015-WT                                            | Y2145    | 34671<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (ITE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 2 IIC                                 | Entra A 2 KIT IIC 10 75<br>Entra A 2 KIT IIC 10 85                                                                                                                                                               | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-00082-RP                                             | Y2145    | 34672          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (ITE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 1 IIC                                 | Entra A 1 KIT IIC 10 75<br>Entra A 1 KIT IIC 10 85                                                                                                                                                               | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-00082-RP                                             | Y2145    | 34672          | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (ITE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 2 CIC                                 | Entra A 2 KIT 10 75<br>Entra A 2 KIT 10 75 PB<br>Entra A 2 KIT 10 85<br>Entra A 2 KIT 10 85 PB<br>Entra A 2 KIT 10 NFM 75<br>Entra A 2 KIT 10 NFM 75 PB<br>Entra A 2 KIT 10 NFM 85<br>Entra A 2 KIT 10 NFM 85 PB | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-00082-RP                                             | Y2145    | 34672<br>38049 | 0310             | 1009     |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S    | DK-MF-000001270 | HI (ITE)                 | Bernafon      | Entra A                                      | Bernafon Entra A 1 CIC                                 | Entra A 1 KIT 10 75<br>Entra A 1 KIT 10 75 PB<br>Entra A 1 KIT 10 85<br>Entra A 1 KIT 10 85 PB<br>Entra A 1 KIT 10 NFM 75<br>Entra A 1 KIT 10 NFM 75 PB<br>Entra A 1 KIT 10 NFM 85<br>Entra A 1 KIT 10 NFM 85 PB | N/A                                                                  | Class Ila       | 2022.08.10                                               | 57144640-HI-00082-RP                                             | Y2145    | 34672<br>38049 | 0310             | 1009     |

|                                    |                 |                 |          |          |         |                           |                                                                                                                                                                                                                                                                                                       |     |           |            |                      |       |                |      |      |
|------------------------------------|-----------------|-----------------|----------|----------|---------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-----------|------------|----------------------|-------|----------------|------|------|
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 2 ITC    | Entra A 2 KIT 312 2.4G NFM 85<br>Entra A 2 KIT 312 2.4G NFM 85 PB<br>Entra A 2 KIT 312 2.4G NFM<br>Entra A 2 KIT 312 2.4G NFM 85<br>Entra A 2 KIT 312 2.4G NFM PB<br>Entra A 2 KIT 312 NFM<br>Entra A 2 KIT 312 NFM PB                                                                                | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 1 ITC    | Entra A 1 KIT 312 2.4G NFM 85<br>Entra A 1 KIT 312 2.4G NFM 85 PB<br>Entra A 1 KIT 312 2.4G NFM<br>Entra A 1 KIT 312 2.4G NFM PB<br>Entra A 1 KIT 312 NFM 85<br>Entra A 1 KIT 312 NFM 85 PB<br>Entra A 1 KIT 312 NFM<br>Entra A 1 KIT 312 NFM PB                                                      | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 2 ITE HS | Entra A 2 KIT 312 2.4G NFM 85<br>Entra A 2 KIT 312 2.4G NFM 85 PB<br>Entra A 2 KIT 312 2.4G NFM<br>Entra A 2 KIT 312 2.4G NFM PB<br>Entra A 2 KIT 312 NFM 85<br>Entra A 2 KIT 312 NFM 85 PB<br>Entra A 2 KIT 312 NFM<br>Entra A 2 KIT 312 NFM PB<br>Entra A 2 KIT 13 2.4G NFM<br>Entra A 2 KIT 13 NFM | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 1 ITE HS | Entra A 1 KIT 312 2.4G NFM 85<br>Entra A 1 KIT 312 2.4G NFM 85 PB<br>Entra A 1 KIT 312 2.4G NFM<br>Entra A 1 KIT 312 2.4G NFM PB<br>Entra A 1 KIT 312 NFM 85<br>Entra A 1 KIT 312 NFM 85 PB<br>Entra A 1 KIT 312 NFM<br>Entra A 1 KIT 312 NFM PB<br>Entra A 1 KIT 13 2.4G NFM<br>Entra A 1 KIT 13 NFM | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 2 ITE FS | Entra A 2 KIT 312 2.4G NFM 85<br>Entra A 2 KIT 312 2.4G NFM 85 PB<br>Entra A 2 KIT 312 2.4G NFM<br>Entra A 2 KIT 312 2.4G NFM PB<br>Entra A 2 KIT 312 NFM 85<br>Entra A 2 KIT 312 NFM 85 PB<br>Entra A 2 KIT 312 NFM<br>Entra A 2 KIT 312 NFM PB<br>Entra A 2 KIT 13 2.4G NFM<br>Entra A 2 KIT 13 NFM | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra A | Bernafon Entra A 1 ITE FS | Entra A 1 KIT 312 2.4G NFM 85<br>Entra A 1 KIT 312 2.4G NFM 85 PB<br>Entra A 1 KIT 312 2.4G NFM<br>Entra A 1 KIT 312 2.4G NFM PB<br>Entra A 1 KIT 312 NFM 85<br>Entra A 1 KIT 312 NFM 85 PB<br>Entra A 1 KIT 312 NFM<br>Entra A 1 KIT 312 NFM PB<br>Entra A 1 KIT 13 2.4G NFM<br>Entra A 1 KIT 13 NFM | N/A | Class IIa | 2022.08.10 | 57144640-HI-00082-RP | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 9 IIC      | Alpha 9 KIT IIC 10 75<br>Alpha 9 KIT IIC 10 90                                                                                                                                                                                                                                                        | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 7 IIC      | Alpha 7 KIT IIC 10 75<br>Alpha 7 KIT IIC 10 90                                                                                                                                                                                                                                                        | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 5 IIC      | Alpha 5 KIT IIC 10 75<br>Alpha 5 KIT IIC 10 90                                                                                                                                                                                                                                                        | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 3 IIC      | Alpha 3 KIT IIC 10 75<br>Alpha 3 KIT IIC 10 90                                                                                                                                                                                                                                                        | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 1 IIC      | Alpha 1 KIT IIC 10 75<br>Alpha 1 KIT IIC 10 90                                                                                                                                                                                                                                                        | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 9 CIC      | Alpha 9, KIT 10 75<br>Alpha 9, KIT 10 75 PB<br>Alpha 9, KIT 10 90<br>Alpha 9, KIT 10 90 PB<br>Alpha 9, KIT 10 NFM 75<br>Alpha 9, KIT 10 NFM 75 PB<br>Alpha 9, KIT 10 NFM 90<br>Alpha 9, KIT 10 NFM 90 PB                                                                                              | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha   | Bernafon Alpha 7 CIC      | Alpha 7, KIT 10 75<br>Alpha 7, KIT 10 75 PB<br>Alpha 7, KIT 10 90<br>Alpha 7, KIT 10 90 PB<br>Alpha 7, KIT 10 NFM 75<br>Alpha 7, KIT 10 NFM 75 PB<br>Alpha 7, KIT 10 NFM 90<br>Alpha 7, KIT 10 NFM 90 PB                                                                                              | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |

|                                    |                 |                 |          |          |       |                         |                                                                                                                                                                                                                                          |     |           |            |                      |       |                |      |      |
|------------------------------------|-----------------|-----------------|----------|----------|-------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-----------|------------|----------------------|-------|----------------|------|------|
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 5 CIC    | Alpha 5, KIT 10 75<br>Alpha 5, KIT 10 75 PB<br>Alpha 5, KIT 10 90<br>Alpha 5, KIT 10 90 PB<br>Alpha 5, KIT 10 NFM 75<br>Alpha 5, KIT 10 NFM 75 PB<br>Alpha 5, KIT 10 NFM 90<br>Alpha 5, KIT 10 NFM 90 PB                                 | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 3 CIC    | Alpha 3, KIT 10 75<br>Alpha 3, KIT 10 75 PB<br>Alpha 3, KIT 10 90<br>Alpha 3, KIT 10 90 PB<br>Alpha 3, KIT 10 NFM 75<br>Alpha 3, KIT 10 NFM 75 PB<br>Alpha 3, KIT 10 NFM 90<br>Alpha 3, KIT 10 NFM 90 PB                                 | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 1 CIC    | Alpha 1, KIT 10 75<br>Alpha 1, KIT 10 75 PB<br>Alpha 1, KIT 10 90<br>Alpha 1, KIT 10 90 PB<br>Alpha 1, KIT 10 NFM 75<br>Alpha 1, KIT 10 NFM 75 PB<br>Alpha 1, KIT 10 NFM 90<br>Alpha 1, KIT 10 NFM 90 PB                                 | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 9 ITC    | Alpha 9, KIT 312 2.4G NFM 90<br>Alpha 9, KIT 312 2.4G NFM 90 PB<br>Alpha 9, KIT 312 2.4G NFM<br>Alpha 9, KIT 312 2.4G NFM PB<br>Alpha 9, KIT 312 NFM 90<br>Alpha 9, KIT 312 NFM 90 PB<br>Alpha 9, KIT 312 NFM<br>Alpha 9, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 7 ITC    | Alpha 7, KIT 312 2.4G NFM 90<br>Alpha 7, KIT 312 2.4G NFM 90 PB<br>Alpha 7, KIT 312 2.4G NFM<br>Alpha 7, KIT 312 2.4G NFM PB<br>Alpha 7, KIT 312 NFM 90<br>Alpha 7, KIT 312 NFM 90 PB<br>Alpha 7, KIT 312 NFM<br>Alpha 7, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 5 ITC    | Alpha 5, KIT 312 2.4G NFM 90<br>Alpha 5, KIT 312 2.4G NFM 90 PB<br>Alpha 5, KIT 312 2.4G NFM<br>Alpha 5, KIT 312 2.4G NFM PB<br>Alpha 5, KIT 312 NFM 90<br>Alpha 5, KIT 312 NFM 90 PB<br>Alpha 5, KIT 312 NFM<br>Alpha 5, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 3 ITC    | Alpha 3, KIT 312 2.4G NFM 90<br>Alpha 3, KIT 312 2.4G NFM 90 PB<br>Alpha 3, KIT 312 2.4G NFM<br>Alpha 3, KIT 312 2.4G NFM PB<br>Alpha 3, KIT 312 NFM 90<br>Alpha 3, KIT 312 NFM 90 PB<br>Alpha 3, KIT 312 NFM PB<br>Alpha 3, KIT 312 NFM | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 1 ITC    | Alpha 1, KIT 312 2.4G NFM 90<br>Alpha 1, KIT 312 2.4G NFM 90 PB<br>Alpha 1, KIT 312 2.4G NFM<br>Alpha 1, KIT 312 2.4G NFM PB<br>Alpha 1, KIT 312 NFM 90<br>Alpha 1, KIT 312 NFM 90 PB<br>Alpha 1, KIT 312 NFM PB<br>Alpha 1, KIT 312 NFM | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha | Bernafon Alpha 9 ITE HS | Alpha 9, KIT 312 2.4G NFM 90<br>Alpha 9, KIT 312 2.4G NFM 90 PB<br>Alpha 9, KIT 312 2.4G NFM<br>Alpha 9, KIT 312 2.4G NFM PB<br>Alpha 9, KIT 312 NFM 90<br>Alpha 9, KIT 312 NFM 90 PB<br>Alpha 9, KIT 312 NFM PB<br>Alpha 9, KIT 312 NFM | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |

|                                    |                 |                 |          |          |          |                             |                                                                                                                                                                                                                                          |     |           |            |                      |       |                |      |      |
|------------------------------------|-----------------|-----------------|----------|----------|----------|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-----------|------------|----------------------|-------|----------------|------|------|
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 7 ITE HS     | Alpha 7, KIT 312 2.4G NFM 90<br>Alpha 7, KIT 312 2.4G NFM 90 PB<br>Alpha 7, KIT 312 2.4G NFM<br>Alpha 7, KIT 312 2.4G NFM PB<br>Alpha 7, KIT 312 NFM 90<br>Alpha 7, KIT 312 NFM 90 PB<br>Alpha 7, KIT 312 NFM PB<br>Alpha 7, KIT 312 NFM | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 5 ITE HS     | Alpha 5, KIT 312 2.4G NFM 90<br>Alpha 5, KIT 312 2.4G NFM 90 PB<br>Alpha 5, KIT 312 2.4G NFM<br>Alpha 5, KIT 312 2.4G NFM PB<br>Alpha 5, KIT 312 NFM 90<br>Alpha 5, KIT 312 NFM 90 PB<br>Alpha 5, KIT 312 NFM PB<br>Alpha 5, KIT 312 NFM | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 3 ITE HS     | Alpha 3, KIT 312 2.4G NFM 90<br>Alpha 3, KIT 312 2.4G NFM 90 PB<br>Alpha 3, KIT 312 2.4G NFM<br>Alpha 3, KIT 312 2.4G NFM PB<br>Alpha 3, KIT 312 NFM 90<br>Alpha 3, KIT 312 NFM 90 PB<br>Alpha 3, KIT 312 NFM<br>Alpha 3, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 1 ITE HS     | Alpha 1, KIT 312 2.4G NFM 90<br>Alpha 1, KIT 312 2.4G NFM 90 PB<br>Alpha 1, KIT 312 2.4G NFM<br>Alpha 1, KIT 312 2.4G NFM PB<br>Alpha 1, KIT 312 NFM 90<br>Alpha 1, KIT 312 NFM 90 PB<br>Alpha 1, KIT 312 NFM<br>Alpha 1, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 9 ITE FS     | Alpha 9, KIT 312 2.4G NFM 90<br>Alpha 9, KIT 312 2.4G NFM 90 PB<br>Alpha 9, KIT 312 2.4G NFM<br>Alpha 9, KIT 312 2.4G NFM PB<br>Alpha 9, KIT 312 NFM 90<br>Alpha 9, KIT 312 NFM 90 PB<br>Alpha 9, KIT 312 NFM<br>Alpha 9, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 7 ITE FS     | Alpha 7, KIT 312 2.4G NFM 90<br>Alpha 7, KIT 312 2.4G NFM 90 PB<br>Alpha 7, KIT 312 2.4G NFM<br>Alpha 7, KIT 312 2.4G NFM PB<br>Alpha 7, KIT 312 NFM 90<br>Alpha 7, KIT 312 NFM 90 PB<br>Alpha 7, KIT 312 NFM<br>Alpha 7, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 5 ITE FS     | Alpha 5, KIT 312 2.4G NFM 90<br>Alpha 5, KIT 312 2.4G NFM 90 PB<br>Alpha 5, KIT 312 2.4G NFM<br>Alpha 5, KIT 312 2.4G NFM PB<br>Alpha 5, KIT 312 NFM 90<br>Alpha 5, KIT 312 NFM 90 PB<br>Alpha 5, KIT 312 NFM<br>Alpha 5, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 3 ITE FS     | Alpha 3, KIT 312 2.4G NFM 90<br>Alpha 3, KIT 312 2.4G NFM 90 PB<br>Alpha 3, KIT 312 2.4G NFM<br>Alpha 3, KIT 312 2.4G NFM PB<br>Alpha 3, KIT 312 NFM 90<br>Alpha 3, KIT 312 NFM 90 PB<br>Alpha 3, KIT 312 NFM<br>Alpha 3, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Alpha    | Bernafon Alpha 1 ITE FS     | Alpha 1, KIT 312 2.4G NFM 90<br>Alpha 1, KIT 312 2.4G NFM 90 PB<br>Alpha 1, KIT 312 2.4G NFM<br>Alpha 1, KIT 312 2.4G NFM PB<br>Alpha 1, KIT 312 NFM 90<br>Alpha 1, KIT 312 NFM 90 PB<br>Alpha 1, KIT 312 NFM<br>Alpha 1, KIT 312 NFM PB | N/A | Class IIa | 2022.09.15 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (BTE) | Bernafon | Alpha XT | Bernafon Alpha XT 9 MNB T   | N/A                                                                                                                                                                                                                                      | N/A | Class IIa | 2023.02.08 | 57144640-HI-00053-RB | Y2145 | 34671<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (BTE) | Bernafon | Alpha XT | Bernafon Alpha XT 7 MNB T   | N/A                                                                                                                                                                                                                                      | N/A | Class IIa | 2023.02.08 | 57144640-HI-00053-RB | Y2145 | 34671<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (BTE) | Bernafon | Alpha XT | Bernafon Alpha XT 5 MNB T   | N/A                                                                                                                                                                                                                                      | N/A | Class IIa | 2023.02.08 | 57144640-HI-00053-RB | Y2145 | 34671<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (BTE) | Bernafon | Alpha XT | Bernafon Alpha XT 9 MNB T R | N/A                                                                                                                                                                                                                                      | N/A | Class IIa | 2023.02.08 | 57144640-HI-00053-RB | Y2145 | 34671<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (BTE) | Bernafon | Alpha XT | Bernafon Alpha XT 7 MNB T R | N/A                                                                                                                                                                                                                                      | N/A | Class IIa | 2023.02.08 | 57144640-HI-00053-RB | Y2145 | 34671<br>38049 | 0310 | 1009 |

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|                                    |                 |                 |          |          |         |                            |                                                                                                          |     |           |            |                      |       |                |      |      |
|------------------------------------|-----------------|-----------------|----------|----------|---------|----------------------------|----------------------------------------------------------------------------------------------------------|-----|-----------|------------|----------------------|-------|----------------|------|------|
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra B | Bernafon Entra B 10 ITC    | Entra B 10 KIT 312 2.4G NFM<br>Entra B 10 KIT 312 NFM                                                    | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra B | Bernafon Entra B 20 ITE HS | Entra B 20 KIT 312 2.4G NFM<br>Entra B 20 KIT 312 NFM                                                    | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra B | Bernafon Entra B 20 ITE FS | Entra B 20 KIT 312 2.4G NFM<br>Entra B 20 KIT 312 NFM                                                    | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra B | Bernafon Entra B 10 ITE HS | Entra B 10 KIT 312 2.4G NFM<br>Entra B 10 KIT 312 NFM                                                    | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Entra B | Bernafon Entra B 10 ITE FS | Entra B 10 KIT 312 2.4G NFM<br>Entra B 10 KIT 312 NFM                                                    | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 400 IIC   | Encanta 400 KIT IIC 10 75<br>Encanta 400 KIT IIC 10 90                                                   | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 400 CIC   | Encanta 400 KIT 10 75<br>Encanta 400 KIT 10 90<br>Encanta 400 KIT 10 NFM 75<br>Encanta 400 KIT 10 NFM 90 | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 300 IIC   | Encanta 300 KIT IIC 10 75<br>Encanta 300 KIT IIC 10 90                                                   | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 300 CIC   | Encanta 300 KIT 10 75<br>Encanta 300 KIT 10 90<br>Encanta 300 KIT 10 NFM 75<br>Encanta 300 KIT 10 NFM 90 | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 200 IIC   | Encanta 200 KIT IIC 10 75<br>Encanta 200 KIT IIC 10 90                                                   | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 200 CIC   | Encanta 200 KIT 10 75<br>Encanta 200 KIT 10 90<br>Encanta 200 KIT 10 NFM 75<br>Encanta 200 KIT 10 NFM 90 | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 100 IIC   | Encanta 100 KIT IIC 10 75<br>Encanta 100 KIT IIC 10 90                                                   | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672          | 0310 | 1009 |
| G10 003348 0004 Rev. 00 (Bernafon) | SBO Hearing A/S | DK-MF-000001270 | HI (ITE) | Bernafon | Encanta | Bernafon Encanta 100 CIC   | Encanta 100 KIT 10 75<br>Encanta 100 KIT 10 90<br>Encanta 100 KIT 10 NFM 75<br>Encanta 100 KIT 10 NFM 90 | N/A | Class IIa | 2025.02.06 | 57144640-HI-00077-RZ | Y2145 | 34672<br>38049 | 0310 | 1009 |

Signed on behalf of SBO Hearing A/S

Date: 2025-04-22

PRRC (name): Mette Bang Dyhrberg

Signature:

