



State of document: ***Released***

Document Number: ***Doc-00072426***

Revision: ***5***

Title: ***EU MDR Product List***

Owner: ***Anja Ravn, anjm***

Reviewed by (Name, Initials, Date, Time):

Approved by (Name, Initials, Date, Time):

***[Isberg Jernby, Karolin (kije) 13-Jul-2022 20:50:21 CEST]***

Released by (Name, Initials, Date, Time):

***[Anja Ravn (anjm) 01-Aug-2022 09:01:59 CEST]***

Implemented (Date, Time):

Obsoleted by (Name, Initials, Date, Time):

File names:

***Doc-00072426\_xlsx.xlsx ver.3, EU MDR Product List rev 4\_signed.pdf ver.1***

EU QMS Certificate No., rev.	Product Type	Product identification (Medical Device Description / Article name)	Article/Model no.	Class EU MDR	Placed on the market (Date of signed EU MDR DoC)	Basic UDI	UDI-DI	Device Group (CND)	GMDN	MDA/MDN	MDS	MDT
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, CBE	186777	Ila	2022-01-14	57121491000182	5712149025350	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, TC	186778	Ila	2022-01-14	57121491000182	5712149025367	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, SIL	186779	Ila	2022-01-14	57121491000182	5712149025374	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, STG	186780	Ila	2022-01-14	57121491000182	5712149025381	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, CNB	186781	Ila	2022-01-14	57121491000182	5712149025398	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4, DBL	186782	Ila	2022-01-14	57121491000182	5712149025404	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 4 DEMO, TERRACOTTA	201386	Ila	2022-01-14	57121491000182	5712149025411	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, SIL	223155	Ila	2021-08-26	57121491000182	5712149026319	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CBE	223156	Ila	2021-08-26	57121491000182	5712149026432	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, TC	223157	Ila	2021-08-26	57121491000182	5712149026449	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CNB	223158	Ila	2021-08-26	57121491000182	5712149026456	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, STG	223159	Ila	2021-08-26	57121491000182	5712149026463	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, DBL	223160	Ila	2021-08-26	57121491000182	5712149026470	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI DEMO, DIAMOND BLACK	227042	Ila	2021-08-26	57121491000182	5712149026487	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHS, SALES PACK 2021.2 USB UK	226479	Ila	2021-08-26	57121491000284	5712149026807	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHS, SALES PACK 2021.2 DVD UK	226483	Ila	2021-08-26	57121491000284	5712149026814	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	ISO FILE, GENIE MEDICAL BAHS 2021.2 US VA	226713	Ila	2021-08-26	57121491000284	5712149026890	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHS, SALES PACK 2022.1 DVD UK	235649	Ila	2022-03-31	57121491000284	5712149026982	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHS, SALES PACK 2022.1 USB UK	235639	Ila	2022-03-31	57121491000284	5712149026975	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHS, SALES PACK 2022.1 US VA	235658	Ila	2022-03-31	57121491000284	5712149027002	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Fitting software	ISO FILE, GENIE MEDICAL BAHS 2022.1 UK	235655	Ila	2022-03-31	57121491000284	5712149026999	Z12040282	60211	0315	N/A	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, SIL	223161	Ila	2022-03-31	57121491000182	5712149026494	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, CBE	223162	Ila	2022-03-31	57121491000182	5712149026500	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, TC	223163	Ila	2022-03-31	57121491000182	5712149026517	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, CNB	223164	Ila	2022-03-31	57121491000182	5712149026524	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, STG	223165	Ila	2022-03-31	57121491000182	5712149026531	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, DBL	223166	Ila	2022-03-31	57121491000182	5712149026548	Y214599	62209	0310	1009	2011
G10 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER DEMO, DIAMOND BLACK	227043	Ila	2022-03-31	57121491000182	5712149026555	Y214599	62209	0310	1009	2011

Signed on behalf of Oticon Medical AB  
Date: 2022-07-08  
PRRC: Karolin Isberg Jernby  
Signature:

**Change Log**

Revision	Description
0	EU MDR Product list layout issued. Use of list and reference added in Doc-00060992 RA procedure.
1	Addition of Ponto 5 Mini & Genie Medical BAHS 2021.2 devices.
2	CO 2037 Ponto 4 items added - released under MDR. Correction to state Basic UDI instead of Basic UDI-DI and addition of column with UDI-DI <del>Correction of information for Ponto 5 Mini &amp; Genie Medical BAHS 2021.2 devices.</del>
3	CO2104/CO2089 addition of Genie Medical BAHS 2022.1 and Ponto 5 SuperPower articles.
4	CO2121 addition of additional article numbers to be used in Australia for Ponto 4 and Ponto 5 mini articles.

EU MDR Product List  
Legal Manufacturer:  
SRN: SE-MF-000000724

Oricon Medical AB, Datavägen 37B, SE-43632 Askim,Sweden

EU QMS Certificate No., rev.	Product Type	Product Identification (Medical Device Description / Article name)	Article / Model no.	Class EU MDR	Placed on the market (Date of signed EU MDR DoC)	Basic UDI	UDI-UDI	Device Group (CMD)	GMDN	MDA/MDN	MDS	MDT
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, CBE	186777	Ila	2022-01-14	57121491000182	5712149025350	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, TC	186778	Ila	2022-01-14	57121491000182	5712149025367	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, SIL	186779	Ila	2022-01-14	57121491000182	5712149025374	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, STG	186780	Ila	2022-01-14	57121491000182	5712149025381	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, CNB	186781	Ila	2022-01-14	57121491000182	5712149025398	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, DBL	186782	Ila	2022-01-14	57121491000182	5712149025404	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4 DEMO, TERRACOTTA	201386	Ila	2022-05-20	57121491000182	5712149025411	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, CBE	252642	Ila	2022-05-20	57121491000182	5712149027095	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, TC	252643	Ila	2022-05-20	57121491000182	5712149027101	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, SIL	252644	Ila	2022-05-20	57121491000182	5712149027118	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, STG	252645	Ila	2022-05-20	57121491000182	5712149027125	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, CNB	252646	Ila	2022-05-20	57121491000182	5712149027132	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 4, DBL	252647	Ila	2022-05-20	57121491000182	5712149027149	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, SIL	223155	Ila	2021-08-26	57121491000182	5712149027156	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CBE	223156	Ila	2021-08-26	57121491000182	5712149026839	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, TC	223157	Ila	2021-08-26	57121491000182	5712149026846	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CNB	223158	Ila	2021-08-26	57121491000182	5712149026853	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, STG	223159	Ila	2021-08-26	57121491000182	5712149026860	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, DBL	223160	Ila	2021-08-26	57121491000182	5712149026867	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI DEMO, DIAMOND BLACK	227642	Ila	2022-05-20	57121491000182	5712149025487	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, SIL	252828	Ila	2022-05-20	57121491000182	5712149027163	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CBE	252829	Ila	2022-05-20	57121491000182	5712149027170	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, TC	252830	Ila	2022-05-20	57121491000182	5712149027187	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, CNB	252831	Ila	2022-05-20	57121491000182	5712149027194	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, STG	252832	Ila	2022-05-20	57121491000182	5712149027200	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 MINI, DBL	252833	Ila	2022-05-20	57121491000182	5712149027217	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHs SALES PACK 2021.2 US UK	226479	Ila	2021-08-26	57121491000284	5712149026807	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHs SALES PACK 2021.2 DVP UK	226483	Ila	2021-08-26	57121491000284	5712149026814	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Fitting software	ISO FILE, GENIE MEDICAL BAHs 2021.2 US VA	226713	Ila	2021-08-26	57121491000284	5712149026880	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHs SALES PACK 2021.1 DVP UK	235649	Ila	2022-03-31	57121491000284	5712149026982	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHs SALES PACK 2021.1 US UK	235658	Ila	2022-03-31	57121491000284	5712149026975	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Fitting software	GENIE MEDICAL BAHs SALES PACK 2021.1 US VA	235655	Ila	2022-03-31	57121491000284	5712149026999	Z12040282	60211	0315	N/A	2011
GI0 106872 0003 Rev. 00	Sound processors	ISO FILE, GENIE MEDICAL BAHs 2021.1 UK	223161	Ila	2022-03-31	57121491000182	5712149026494	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, SIL	223162	Ila	2022-03-31	57121491000182	5712149026500	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, TC	223163	Ila	2022-03-31	57121491000182	5712149026517	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, CNB	223164	Ila	2022-03-31	57121491000182	5712149026524	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, STG	223165	Ila	2022-03-31	57121491000182	5712149026531	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER, DBL	223166	Ila	2022-03-31	57121491000182	5712149026548	Y214599	62209	0310	1009	2011
GI0 106872 0003 Rev. 00	Sound processors	PONTO 5 SUPERPOWER DEMO, DIAMOND BLACK	227643	Ila	2022-03-31	57121491000182	5712149026555	Y214599	62209	0310	1009	2011

Signed on behalf of Oricon Medical AB

Date: 2022-05-20

PRIC: Karolín, Isberg Järby

Signature: 