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ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0141 Rev. 02

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A

6020 Innsbruck

AUSTRIA

Product:

Cochlear Implants

**Auditory Brainstem Implants and related
Accessories**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713174201, 713169203, 713173997

Valid from:

2020-04-30

Valid until:

2024-04-25

Date,

2020-04-30

Christoph Dicks

Head of Certification/Notified Body



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No. I7 017853 0141 Rev. 02

Model(s): see below

Product: Cochlear Implants
(Implant variants listed below are MR Conditional -
see product labeling for information for use in MR
environment)

Test Report No.: 713036349

Model:	Variant:	Model no.:
Mi1200 SYNCHRONY PIN	+ Standard Electrode	09396
Mi1200 SYNCHRONY		09395
Mi1200 SYNCHRONY PIN	+ Compressed Electrode	09397
Mi1200 SYNCHRONY		09408
Mi1200 SYNCHRONY PIN	+ Medium Electrode	09399
Mi1200 SYNCHRONY		09398
Mi1200 SYNCHRONY PIN	+ FLEX ²⁴ Electrode	09401
Mi1200 SYNCHRONY		09400
Mi1200 SYNCHRONY PIN	+ FLEX ^{SOFT} Electrode	09403
Mi1200 SYNCHRONY		09402
Mi1200 SYNCHRONY PIN	+FLEX ²⁸ Electrode	09405
Mi1200 SYNCHRONY		09404
Mi1200 SYNCHRONY PIN	+FORM ¹⁹ Electrode	30893
Mi1200 SYNCHRONY		30892
Mi1200 SYNCHRONY PIN	+FORM ²⁴ Electrode	30895
Mi1200 SYNCHRONY		30894
Mi1200 SYNCHRONY PIN	+FLEX ^{20W} Electrode	30897
Mi1200 SYNCHRONY		30896



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No. I7 017853 0141 Rev. 02

Test Report No.:	713075507	
Model:	Variant:	Model no.:
Mi1210 SYNCHRONY ST	+ Standard Electrode	33182
Mi1210 SYNCHRONY ST	+ Compressed Electrode	33184
Mi1210 SYNCHRONY ST	+ Medium Electrode	33183
Mi1210 SYNCHRONY ST	+ FLEX ²⁴ Electrode	33186
Mi1210 SYNCHRONY ST	+ FLEX ^{SOFT} Electrode	33185
Mi1210 SYNCHRONY ST	+FLEX ²⁸ Electrode	33187
Mi1210 SYNCHRONY ST	+FORM ¹⁹ Electrode	33188
Mi1210 SYNCHRONY ST	+FORM ²⁴ Electrode	33189
Mi1210 SYNCHRONY ST	+FLEX ²⁰ Electrode	33191

Product: **Auditory Brainstem Implants**
(Implant variants listed below are MR Conditional-
see product labeling for information for use in MR
environment)

Test Report No.:	713036349	
Model:	Variant:	Model no.:
Mi1200 SYNCHRONY PIN	ABI	09407
Mi1200 SYNCHRONY		09406



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No. I7 017853 0141 Rev. 02

Product: Accessories for Cochlear Implant Systems and
for Auditory Brainstem Implant Systems

Test Report No.: 713036349

Model:

Model no.:

Mi1200 Implant Template PIN
Mi1200 Implant Template

09800
09799

Product: Cochlear Implants
(Implant variants listed below are MR conditional-
see Product labeling for information for use
in MR environment)

Test Report No.: 713037694

Model:

Variant:

Model no.:

Mi1200 SYNCHRONY PIN
Mi1200 SYNCHRONY

+FLEX²⁰ Electrode

07882
07880

Product: Accessories for Cochlear Implant Systems

Test Report No.: 713075507

Model:

Model no.:

Mi1210 Implant Template

33056



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No. I7 017853 0141 Rev. 02

Product:

Cochlear Implants

(Implant variants listed below are MR Conditional-
see product labelling for information for use in MR
conditional

Test Report No.:

713129314

Model:

Variant:

Model no.:

Mi1200 SYNCHRONY PIN
Mi1200 SYNCHRONY
Mi1210 SYNCHRONY ST

+FLEX²⁶ Electrode
+FLEX²⁶ Electrode
+FLEX²⁶ Electrode

36618
36617
36619

Product:

Cochlear Implants

(Implant variants listed below are MR Conditional-
see product labelling for information for use in MR
conditional

Test Report No.:

713150923

Model:

Variant:

Model No.:

Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN
Mi1250 SYNCHRONY 2 PIN

STANDARD Electrode
MEDIUM Electrode
COMPRESSED Electrode
FLEXSOFT Electrode
FLEX²⁰ Electrode
FLEX²⁴ Electrode
FLEX²⁶ Electrode

36671
36673
36675
36677
37174
36679
36901

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Mi1250 SYNCHRONY 2 PIN	FLEX ²⁸ Electrode	36681
Mi1250 SYNCHRONY 2 PIN	FORM ¹⁹ Electrode	37176
Mi1250 SYNCHRONY 2 PIN	FORM ²⁴ Electrode	37178
Mi1250 SYNCHRONY 2	STANDARD Electrode	36672
Mi1250 SYNCHRONY 2	MEDIUM Electrode	36674
Mi1250 SYNCHRONY 2	COMPRESSED Electrode	36676
Mi1250 SYNCHRONY 2	FLEX ^{SOFT} Electrode	36678
Mi1250 SYNCHRONY 2	FLEX ²⁰ Electrode	37175
Mi1250 SYNCHRONY 2	FLEX ²⁴ Electrode	36680
Mi1250 SYNCHRONY 2	FLEX ²⁶ Electrode	36902
Mi1250 SYNCHRONY 2	FLEX ²⁸ Electrode	36682
Mi1250 SYNCHRONY 2	FORM ¹⁹ Electrode	37177
Mi1250 SYNCHRONY 2	FORM ²⁴ Electrode	37179



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No. I7 017853 0141 Rev. 02

Test Report No.: 713173997

Model:	Variant:	Model no.:
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁰ SL	38801
Mi1250 SYNCHRONY 2	FLEX ²⁰ SL	38802
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁴ SL	38803
Mi1250 SYNCHRONY 2	FLEX ²⁴ SL	38804
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁶ SL	38805
Mi1250 SYNCHRONY 2	FLEX ²⁶ SL	38806
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁸ SL	38807
Mi1250 SYNCHRONY 2	FLEX ²⁸ SL	38808
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁰ SL S-Vector Magnet	39554
Mi1250 SYNCHRONY 2	FLEX ²⁰ SL S-Vector Magnet	39555
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁴ SL S-Vector Magnet	39556
Mi1250 SYNCHRONY 2	FLEX ²⁴ SL S-Vector Magnet	39557
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁶ SL S-Vector Magnet	39558
Mi1250 SYNCHRONY 2	FLEX ²⁶ SL S-Vector Magnet	39559
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁸ SL S-Vector Magnet	39560
Mi1250 SYNCHRONY 2	FLEX ²⁸ SL S-Vector Magnet	39561

Product: Mi1250 SYNCHRONY 2 PIN/Mi1250 SYNCHRONY 2
Cochlear Implant with S-Vector Magnet

Test Report No.: 713169203 / 713174201

Model:	Variant:	Model no.:
Mi1250 SYNCHRONY 2 PIN	STANDARD S-Vector Magnet	39534
Mi1250 SYNCHRONY 2	STANDARD S-Vector Magnet	39535
Mi1250 SYNCHRONY 2 PIN	MEDIUM S-Vector Magnet	39536
Mi1250 SYNCHRONY 2	MEDIUM S-Vector Magnet	39537
Mi1250 SYNCHRONY 2 PIN	COMPRESSED S-Vector Magnet	39538
Mi1250 SYNCHRONY 2	COMPRESSED S-Vector Magnet	39539
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁰ S-Vector Magnet	39548
Mi1250 SYNCHRONY 2	FLEX ²⁰ S-Vector Magnet	39549

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Mi1250 SYNCHRONY 2 PIN	FLEX ²⁴ S-Vector Magnet	39542
Mi1250 SYNCHRONY 2	FLEX ²⁴ S-Vector Magnet	39543
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁶ S-Vector Magnet	39546
Mi1250 SYNCHRONY 2	FLEX ²⁶ S-Vector Magnet	39547
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁸ S-Vector Magnet	39544
Mi1250 SYNCHRONY 2	FLEX ²⁸ S-Vector Magnet	39545
Mi1250 SYNCHRONY 2 PIN	FLEX ^{SOFT} S-Vector Magnet	39540
Mi1250 SYNCHRONY 2	FLEX ^{SOFT} S-Vector Magnet	39541
Mi1250 SYNCHRONY 2 PIN	FORM ¹⁹ S-Vector Magnet	39550
Mi1250 SYNCHRONY 2	FORM ¹⁹ S-Vector Magnet	39551
Mi1250 SYNCHRONY 2 PIN	FORM ²⁴ S-Vector Magnet	39552
Mi1250 SYNCHRONY 2	FORM ²⁴ S-Vector Magnet	39553

Product:

Mi1260 SONATA 2 Cochlear Implant

Model:

Variant:

Model no.:

Mi1260 SONATA 2	STANDARD	38538
Mi1260 SONATA 2	MEDIUM	38539
Mi1260 SONATA 2	COMPRESSED	38540
Mi1260 SONATA 2	FLEX ²⁰	38542
Mi1260 SONATA 2	FLEX ²⁴	38543
Mi1260 SONATA 2	FLEX ²⁶	38544
Mi1260 SONATA 2	FLEX ²⁸	38545
Mi1260 SONATA 2	FLEX ^{SOFT}	38541
Mi1260 SONATA 2	FORM ¹⁹	38546
Mi1260 SONATA 2	FORM ²⁴	38547



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Product:

Accessories for Cochlear Implant Systems

Test Report No. :

713150923

Model:

Model No. :

Mi1250 Implant Template

36894