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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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www.zlg.de
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

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 Mi1200 SYNCHRONY	+ Standard Electrode	09396 09395
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+ Compressed Electrode	09397 09408
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+ Medium Electrode	09399 09398
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+ FLEX ²⁴ Electrode	09401 09400
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+ FLEX ^{SOFT} Electrode	09403 09402
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+FLEX ²⁸ Electrode	09405 09404
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+FORM ¹⁹ Electrode	30893 30892
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+FORM ²⁴ Electrode	30895 30894
Mi1200 SYNCHRONY PIN Mi1200 SYNCHRONY	+FLEX ^{20W} Electrode	30897 30896

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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	+FLEX ²⁶ Electrode	36618
Mi1200 SYNCHRONY	+FLEX ²⁶ Electrode	36617
Mi1210 SYNCHRONY ST	+FLEX ²⁶ Electrode	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	STANDARD Electrode	36671
Mi1250 SYNCHRONY 2 PIN	MEDIUM Electrode	36673
Mi1250 SYNCHRONY 2 PIN	COMPRESSED Electrode	36675
Mi1250 SYNCHRONY 2 PIN	FLEXSOFT Electrode	36677
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁰ Electrode	37174
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁴ Electrode	36679
Mi1250 SYNCHRONY 2 PIN	FLEX ²⁶ Electrode	36901

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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

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