

WALLABY MEDICAL, INC.

EC DECLARATION OF CONFORMITY

Manufacturer	EC Authorized Representative
Wallaby Medical, Inc. 22901 Mill Creek Dr. Laguna Hills, CA 92653 USA	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70 346-7299

Wallaby Medical, Inc. declares that the device or device families listed below comply with the legislation of the member state (NL) where the Notified Body (BSI, CE 2797) is located, transposing the European Medical Device Directive 93/42/EEC for Medical Devices. The official conformity assessment to the Medical Device Directive 93/42/EEC Annex II.3 and Annex II.4. All supporting documentation is retained at the premises of the manufacturer.

Product: Avenir™ Coil System

Type/Model/Classification: See Attachment 1

Standards Applied: A list of Harmonized Standards, for which documented evidence for compliance can be provided; and are included in the Design Dossier.

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands

Certificate Number: Annex II.3 (CE 684927); Annex II.4 (CE 684926)

Effective Date: See Attachment 1

Expiry Date: 2024-05-26



Nate Knock (Director of Quality and Regulatory Affairs)

14MA-12021

Date

Wallaby Medical
EC Declaration of Conformity: Attachment 1

Product Name	Model Number	Primary Wire OD (in)	Secondary Coil OD (mm)	Coil Length (cm)	Class	MDD Annex IX	Start of CE Marking Date
Avenir Coil System	18CFR06016	0.0125	6.0	16	III	Rule 8	2019-08-30
Avenir Coil System	18CFR07019	0.0125	7.0	19	III	Rule 8	2019-08-30
Avenir Coil System	18CFR08027	0.0135	8.0	27	III	Rule 8	2019-08-30
Avenir Coil System	18CFR09030	0.0135	9.0	30	III	Rule 8	2019-08-30
Avenir Coil System	18CFR10034	0.0135	10.0	34	III	Rule 8	2019-08-30
Avenir Coil System	18CFR11037	0.0145	11.0	37	III	Rule 8	2019-08-30
Avenir Coil System	18CFR12040	0.0145	12.0	40	III	Rule 8	2019-08-30
Avenir Coil System	18CFR13043	0.0145	13.0	43	III	Rule 8	2019-08-30
Avenir Coil System	18CFR14047	0.0145	14.0	47	III	Rule 8	2019-08-30
Avenir Coil System	18CFR15050	0.0145	15.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR16050	0.0145	16.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR18050	0.0145	18.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR20050	0.0145	20.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR22050	0.0145	22.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR25050	0.0145	25.0	50	III	Rule 8	2019-08-30
Avenir Coil System	18CFR25060	0.0145	25.0	60	III	Rule 8	2019-08-30
Avenir Coil System	10CFR02002	0.0110	2.0	2	III	Rule 8	2019-08-30
Avenir Coil System	10CFR02003	0.0110	2.0	3	III	Rule 8	2019-08-30
Avenir Coil System	10CFR02006	0.0110	2.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFR02505	0.0110	2.5	5	III	Rule 8	2019-08-30
Avenir Coil System	10CFR03004	0.0110	3.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10CFR03006	0.0110	3.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFR03506	0.0110	3.5	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFR04007	0.0110	4.0	7	III	Rule 8	2019-08-30
Avenir Coil System	10CFR04013	0.0110	4.0	13	III	Rule 8	2019-08-30
Avenir Coil System	10CFR05008	0.0110	5.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10CFR05017	0.0110	5.0	17	III	Rule 8	2019-08-30
Avenir Coil System	10CFR06011	0.0110	6.0	11	III	Rule 8	2019-08-30
Avenir Coil System	10CFR06020	0.0110	6.0	20	III	Rule 8	2019-08-30
Avenir Coil System	10CFR07013	0.0110	7.0	13	III	Rule 8	2019-08-30
Avenir Coil System	10CFR07024	0.0110	7.0	24	III	Rule 8	2019-08-30
Avenir Coil System	10CFR08016	0.0110	8.0	16	III	Rule 8	2019-08-30
Avenir Coil System	10CFR08027	0.0110	8.0	27	III	Rule 8	2019-08-30
Avenir Coil System	10CFR09023	0.0110	9.0	23	III	Rule 8	2019-08-30
Avenir Coil System	10CFR09030	0.0110	9.0	30	III	Rule 8	2019-08-30
Avenir Coil System	10CFR10027	0.0110	10.0	27	III	Rule 8	2019-08-30
Avenir Coil System	10CFR10034	0.0110	10.0	34	III	Rule 8	2019-08-30
Avenir Coil System	10HFL03004	0.0110	3.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFL03006	0.0110	3.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFL03008	0.0110	3.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFL03010	0.0110	3.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04004	0.0110	4.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04006	0.0110	4.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04008	0.0110	4.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04010	0.0110	4.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04015	0.0110	4.0	15	III	Rule 8	2019-08-30
Avenir Coil System	10HFL04020	0.0110	4.0	20	III	Rule 8	2019-08-30
Avenir Coil System	10HFL05010	0.0110	5.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFL05015	0.0110	5.0	15	III	Rule 8	2019-08-30
Avenir Coil System	10HFL05020	0.0110	5.0	20	III	Rule 8	2019-08-30
Avenir Coil System	10HFL06010	0.0110	6.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFL06015	0.0110	6.0	15	III	Rule 8	2019-08-30
Avenir Coil System	10HFL06020	0.0110	6.0	20	III	Rule 8	2019-08-30

Product Name	Model Number	Primary Wire OD (in)	Secondary Coil OD (mm)	Coil Length (cm)	Class	MDD Annex IX	Start of CE Marking Date
Avenir Coil System	10HFL07015	0.0110	7.0	15	III	Rule 8	2019-08-30
Avenir Coil System	10HFL07020	0.0110	7.0	20	III	Rule 8	2019-08-30
Avenir Coil System	10HFL07030	0.0110	7.0	30	III	Rule 8	2019-08-30
Avenir Coil System	10HFL08020	0.0110	8.0	20	III	Rule 8	2019-08-30
Avenir Coil System	10HFL08030	0.0110	8.0	30	III	Rule 8	2019-08-30
Avenir Coil System	10HFL09030	0.0110	9.0	30	III	Rule 8	2019-08-30
Avenir Coil System	10HFL10030	0.0110	10.0	30	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01002	0.0110	1.0	2	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01501	0.0110	1.5	1	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01502	0.0110	1.5	2	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01503	0.0110	1.5	3	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01504	0.0110	1.5	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFN01506	0.0110	1.5	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02001	0.0110	2.0	1	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02002	0.0110	2.0	2	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02003	0.0110	2.0	3	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02004	0.0110	2.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02006	0.0110	2.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02008	0.0110	2.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02503	0.0110	2.5	3	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02504	0.0110	2.5	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFN02506	0.0110	2.5	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03004	0.0110	3.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03006	0.0110	3.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03008	0.0110	3.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03010	0.0110	3.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03504	0.0110	3.5	4	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03506	0.0110	3.5	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN03508	0.0110	3.5	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN04006	0.0110	4.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN04008	0.0110	4.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN04010	0.0110	4.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFN05006	0.0110	5.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN05008	0.0110	5.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN05010	0.0110	5.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10HFN06006	0.0110	6.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10HFN06008	0.0110	6.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10HFN06010	0.0110	6.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10CFN01002	0.0110	1.0	2	III	Rule 8	2019-08-30
Avenir Coil System	10CFN01502	0.0110	1.5	2	III	Rule 8	2019-08-30
Avenir Coil System	10CFN01503	0.0110	1.5	3	III	Rule 8	2019-08-30
Avenir Coil System	10CFN01504	0.0110	1.5	4	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02002	0.0110	2.0	2	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02003	0.0110	2.0	3	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02004	0.0110	2.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02006	0.0110	2.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02503	0.0110	2.5	3	III	Rule 8	2019-08-30
Avenir Coil System	10CFN02504	0.0110	2.5	4	III	Rule 8	2019-08-30
Avenir Coil System	10CFN03004	0.0110	3.0	4	III	Rule 8	2019-08-30
Avenir Coil System	10CFN03006	0.0110	3.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFN03008	0.0110	3.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10CFN03010	0.0110	3.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10CFN04006	0.0110	4.0	6	III	Rule 8	2019-08-30
Avenir Coil System	10CFN04008	0.0110	4.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10CFN04010	0.0110	4.0	10	III	Rule 8	2019-08-30
Avenir Coil System	10CFN05008	0.0110	5.0	8	III	Rule 8	2019-08-30
Avenir Coil System	10CFN05010	0.0110	5.0	10	III	Rule 8	2019-08-30