TF02-6.01.01

Pre-clinical data

(Rev.: 6)

Revision history			
Date	Rev.	Modification Description	Modified by
10/03/2022	1	Creation of the document	Ainara J.
25/08/2022	2	Added AG700 biocompatibility statement to section 1.3 and annexes.	Ainara J.
18/05/2023	3	Sections 1.1, 1.2, 1.3, 1.4, 1.6.3 and 2 updated. Filename updated.	Ainara J.
24/09/2023	4	References to annexes updated.	Ainara J.
09/01/2025	5	Electrical safety and EMC test report for Fesia Grasp added. Biocompatibility test reports for AG700 hydrogel updated.	Ainara J.
07/04/2025	6	Electrical safety and EMC test report for new stimulator STGB added. ELFR intracutaneous reactivity test report added.	Ainara J.

	Last update	Reviewed by	Approved by
Person	Ainara Jimenez	Ainara Jimenez	Haritz Zabaleta
Position	Quality	Quality Manager	PRRC
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Final

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1 PRE-CLINICAL DATA

1.1 Electrical safety

Test description	Standard	LAB	Results
Electrical safety test for Fesia Walk device (STGA)	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. Information technology equipment - Safety - Part 1: General requirements. • IEC 60601-1: 2005 + Corr.1: 2006 + A1: 2012 + IEC 60601-1-11:2015 + IEC 60601-2-10:2012 + A1:2016 + IEC 60950-1:2005 + CORR:2006 + A1:2009 + A2:2013. • EN 60601-1: 2006 + A11: 2011 + A1: 2013 + EN 60601-1-11:2015 + EN 60601-2-10:2015 + EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + AC:2011 + A2:2013. • UNE-EN 60601-1: 2008 + Erratum 2008 + Corr.: 2010 + A11: 2012 + UNE-EN 60601-1-11:2015 + UNE-EN 60601-2-10:2015 + UNE-EN 60950-1:2007 + A11:2009 + CORR:2007 + A1:2011 + A12:2011 + AC:2012 + A2:2015.	DEKRA	SATISFACTORY See annexed report *DEKRA_RSE_Fesia Walk_STGA*
Electrical safety test for Fesia Grasp (STGA)	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. • IEC 60601-1: 2005 + Corr.1: 2006 + AMD1:2012 + AMD2:2020 / IEC 60601-1-11:2015 + A1:2020 / IEC 60601-2-10:2012 + A1:2016 • EN 60601-1: 2006 + A11: 2011 + A1:2013 + A2:2021 / EN 60601-1-11:2015+ A1:2021 / EN 60601-2-10:2015 • UNE-EN 60601-1: 2008 + Erratum 2008 + Corr.: 2010 + A11: 2012 + A12:2015 + A1:2021 / UNE EN 60601-1-11:2015 + A1:2021 / UNE-EN 60601-2-10:2015 + A1:2016	DEKRA	SATISFACTORY See annexed report *DEKRA_RSE_Fesia Grasp_STGA*
Fesia Walk and Fesia Bike (STGB)	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	DEKRA	SATISFACTORY See annexed report *DEKRA_RSE_STGB*

	• IEC 60601-1: 2005 + Corr.1: 2006 + AMD1:2012 + AMD2:2020 / IEC 60601-1-11:2015 + A1:2020 / IEC 60601-2-10:2012 + A1:2016 • EN 60601-1: 2006 + A11: 2011 + A1:2013 + A2:2021 / EN 60601-1-11:2015+ A1:2021 / EN 60601-2-10:2015 • UNE-EN 60601-1: 2008 + Erratum 2008 + Corr.: 2010 + A11: 2012 + A12:2015 + A1:2021 / UNE EN 60601-1-11:2015 + A1:2021 / UNE-EN 60601-2-10:2015 + A1:2016		

1.2 Electromagnetic Compatibility

Test description	Standard	LAB	Results
EMC emissions and immunity test for Fesia Walk (STGA)	• EN 60601-1-2 (2007) / AC (2010): Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. • EN 60601-2-10 (2000) / A1 (2001): Medical electrical equipment. Part 2-10: Particular requirements for the safety of nerve and muscle stimulators. • ETSI EN 301 489-1 V1.9.2 (2011-09): Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements. • ETSI EN 301 489-17 V2.2.1 (2012-09): Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems.	DEKRA	SATISFACTORY See annexed report *DEKRA_EMC_Fesia Walk_STGA*
EMC emissions and immunity test for Fesia Walk (STGA). Additional testing with updated standards.	• UNE-EN 60601-1-2:2015/A1:2021: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. • UNE-EN 60601-2-10:2015/A1:2016: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. • ETSI-EN 301 489-1 v2.2.3 (2019-11): ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements. • ETSI-EN 301 489-17 v3.2.4 (2020-09): ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems.	NAITEC	SATISFACTORY See annexed report *NAITEC_EMC and RSE_Fesia Walk_STGA*
EMC emissions and immunity test for Fesia Grasp (STGA)	• IEC 60601-1-2:2014 + A1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.	DEKRA	SATISFACTORY See annexed report

	• EN 60601-1-2:2015 + A1:2021: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. • IEC 60601-2-10:2023: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.		*DEKRA_EMC_Fesia Grasp*
EMC emissions and immunity test for Fesia Walk and Fesia Bike (STGB)	• ETSI-EN 301 489-1 v2.2.3 (2019-11): ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements. • ETSI-EN 301 489-17 v3.3.0 (2024-07): ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems.	DEKRA	SATISFACTORY See annexed report *DEKRA_EMC_ STGB_001*
EMC emissions and immunity test for Fesia Walk and Fesia Bike (STGB)	• IEC 60601-1-2:2014 + A1:2020 / UNE-EN 60601-1-2:2015/A1:2021: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. • IEC 60601-2-10:2023: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	DEKRA	SATISFACTORY See annexed report *DEKRA_EMC_ STGB_002*

1.3 Biocompatibility

Biocompatibility evaluation and test selection has been made in accordance with EN ISO 10993-1:2020. This process has been documented as part of the Risk management activities in Chapter 5 of this Technical Documentation (TF02-5).

According to the nature of contact with the body, the applied parts of the Fesia stimulation devices are the electrodes which are a surface-contacting device that could be in contact with intact skin.

The duration of contact depends on the use of the device:

- Devices intended for clinical use are intended for use of 1 hour per day, up to 20 sessions. Therefore, in this case, the electrodes should be in contact during a limited time, Type A - Limited exposure (<24h).
- Devices intended for personal use are intended for periods of use of 4 hours, up to 8 hours a day, 7 days a week. Therefore, in this case, the electrodes should be in contact during long time, Type C – Long term exposure (>30 d).

According to table A.1 of EN ISO 10993-1 (Table 1), the biological evaluation of a surface medical device, in contact with intact skin and type A and C contact duration consists of evaluating:

- Physical and/or chemical information.
- Cytotoxicity (EN ISO 10993-5).
- Sensitization (EN ISO 10993-10).
- Irritation or intracutaneous reactivity (EN ISO 10993-23).

Table 1: Endpoints to be tested (Table A.1 of EN ISO 10993-1)

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/developmental toxicity[d,e]	Degradation[f]
Surface medical device	Intact skin	A	X[g]	E[h]	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E		E	E			E					
		C	X	E	E	E		E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		

The materials composing the Fesia electrodes are described in *TF02-1.06.02.01-Specifications of raw materials components*.

The part of the electrodes which is in contact with the skin is the hydrogel from Axelgaard. As materials are not processed by the supplier which only integrates the gel at the top of the conductive plates, we consider that hydrogel cytotoxicity, skin irritation and sensitization test results provide enough biological evaluation information. Additionally, an intracutaneous reactivity test has been carried out for the ELFR electrodes. Table 2 shows these biocompatibility test reports.

Table 2: Biocompatibility reports

Report	LAB	Results
Statement of Confirmation for Biocompatibility Studies of AG700	Intertek	See annexed reports *Statement Biocompatibility AG700,* *AG700 Gap analysis* *Hydrogel gap analysis*
Cytotoxicity for AG700	NAMSA	See annexed report *Cytotoxicity_AG700*
Skin irritation for AG700	NAMSA	See annexed report *Skin Irritation_AG700*
Sensitization for AG700	NAMSA	See report *Sensitization _AG700*
Statement of Confirmation for Biocompatibility Studies of AG800	Intertek	See annexed report *Statement Biocompatibility AG800,* *AG800 Gap analysis* *Hydrogel gap analysis*
Cytotoxicity for MD-7000 (AG800 hydrogel series)	NAMSA	See annexed report *Cytotoxicity-07C 43557 03*
Skin irritation for MD-7000 (AG800 hydrogel series)	NAMSA	See annexed report *Skin Irritation-99C 11876 00*
Sensitization for MD-7000 (AG800 hydrogel series)	NAMSA	See annexed report *Sensitization-99C 11876 00*
Intracutaneous reactivity test report (ELFR electrodes)	Eurofins	See annexed report *ELFR Intracutaneous reactivity test report*

1.4 Device lifetime. Stability / ageing tests

The life of the device is set to 5 years from the date of manufacture. This expiration is determined by the stability of the device conditions as described in the annexed document *Device lifetime rationale*. The adequacy of this time of life of the device has been found by analysis of product samples manufactured for over 5 years.

1.5 Combination / compatibility with other device

No applicable – The product is not intended to be combined with other devices.

1.6 Other preclinical testing

1.6.1 Restriction of the use of certain hazardous substances in electrical and electronic equipment

Test description	Standard	LAB	Results
RoHS	• Annex II of the European Union Directive 2011/65/UE + 2012/50/UE to 2012/51/UE + 2014/1/UE to 2014/16/UE + 2014/69/UE to 2014/76/UE + 2015/573/UE to 2015/574/UE + 2016/585/UE + 2016/1028/UE + 2016/1029/UE	DEKRA	SATISFACTORY See annexed report *DEKRA_RoHS*

1.6.2 RF exposure

Test description	Standard	LAB	Results
RF exposure (STGA)	• IEC 62479:2010	DEKRA	SATISFACTORY See annexed reports *DEKRA_RF_Exposure_STGA_Stimulator* *DEKRA_RF_Exposure_STGA_Sensor*
RF exposure (STGB)	• IEC 62479:2010	DEKRA	SATISFACTORY See annexed reports *DEKRA_RF_Exposure_STGB*

1.6.3 Software validation

Validation tests were performed with satisfactory results. Each software (Firmware, Fesia PRO, MyFesia, Fesia Fitter) has its own test report that can be found in the validation folder of the specific software design and development documentation (TF02-3-Design and manufacturing/TF02-3.02-Product design and development/Annexes/ Software/ *specific software*, where the corresponding and *specific software* must be selected):

- Firmware_R6_REG.7.3-01-A9 Test report
- FesiaPro_R6_REG.7.3-01-A9 Test report
- MyFesia_R3_REG.7.3-01-A9 Test report
- Fesia Fitter_R7_REG.7.3-01-A9 Test report

1.6.4 Transport test

Transport test was performed with satisfactory results (see report TF02-6.01-A11).

2 ANNEXES

- DEKRA_RSE_Fesia Walk_STGA
- DEKRA_RSE_Fesia Walk_STGA_Doc traceability
- DEKRA_RSE_Fesia Walk_STGA_Model name
- DEKRA_RSE_Fesia Grasp_STGA
- DEKRA_RSE_STGB
- DEKRA_EMC_Fesia Walk
- DEKRA_EMC_Fesia Walk_model name rationale
- DEKRA_EMC_Fesia Grasp
- NAITEC_EMC and RSE_Fesia Walk
- Statement Biocompatibility AG700
- Cytotoxicity_AG700
- Skin irritation_AG700
- Sensitization_AG700

- AG700 Gap analysis
- Statement Biocompatibility AG800
- Cytotoxicity-07C 43557 03
- Skin Irritation-99C 11876 00
- Sensitization-99C 11876 00
- Fesia statement 12.11.24
- AG800 Gap analysis
- Hydrogel gap analysis
- ELFR Intracutaneous reactivity test report
- Device lifetime rationale
- DEKRA_RoHS
- DEKRA_RF_Exposure_STGA_Stimulator
- DEKRA_RF_Exposure_STGA_Sensor
- DEKRA_RF Exposure_STGB
- Firmware_R6_REG.7.3-01-A9 Test report
- FesiaPro_R6_REG.7.3-01-A9 Test report
- MyFesia_R3_REG.7.3-01-A9 Test report
- Fesia Fitter_R7_REG.7.3-01-A9 Test report
- Transport test report