Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical electrical equipment Part 1-6
General requirements for safety - Collateral Standard: Usability

Report Number. .....:	***Attachment #2 of Test Report Nº 2116 / 0524***
Date of issue .....:	***See main part of present Test Report***
Total number of pages.....	**14**
Name of Testing Laboratory preparing the Report.....:	**SGS Tecnos, S.A. (Electric Test Laboratory)**
Applicant's name.....:	***See main part of present Test Report***
Address .....:	***See main part of present Test Report***
Test specification:	
Standard .....:	IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)
Test procedure .....:	CE Examination
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1_6G
Test Report Form(s) Originator.....:	TÜV Rheinland of North America
Master TRF.....:	Dated 2017-05

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
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Test item description ..... :		***See main part of present Test Report***
Trade Mark ..... :		***See main part of present Test Report***
Manufacturer ..... :		***See main part of present Test Report***
Model/Type reference ..... :		***See main part of present Test Report***
Ratings ..... :		***See main part of present Test Report***
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
☒	**CB Testing Laboratory:**	**SGS Tecnos, S.A. (Electric Test Laboratory)**
Testing location/ address.....:		C/ Trespaderne, 29 - Edificio Barajas 1 28042 – MADRID (Spain)
Tested by (name, function, signature).....:		*For signature see main part of present Test Report*
Approved by (name, function, signature)...:		*For signature see main part of present Test Report*
☐	~~**Testing procedure: CTF Stage 1:**~~	
☐	~~**Testing procedure: CTF Stage 2:**~~	
☐	~~**Testing procedure: CTF Stage 3:**~~	
☐	~~**Testing procedure: CTF Stage 4:**~~	

List of Attachments (including a total number of pages in each attachment): Appendix I – IEC 62366:2007 + A1:2014 – Usability engineering process checklist (Pages: 7 to 14)	
Summary of testing:	
Tests performed (name of test and test clause): ***See main part of present Test Report***	**Testing location:** **SGS Tecnos, S.A. (Electric Test Laboratory)** **C/ Trespaderne, 29 - Edificio Barajas 1** **28042 – MADRID (Spain)**
Summary of compliance with National Differences (List of countries addressed): ***See main part of present Test Report*** ☒ **The product fulfils the requirements of *see main part of present Test Report***	

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See main part of present Test Report

Test item particulars.....:	
Classification of installation and use.....:	***See main part of present Test Report***
Supply Connection.....:	***See main part of present Test Report***
.....:	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item .....:	***See main part of present Test Report***
Date (s) of performance of tests.....:	***See main part of present Test Report***

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... : ***See main part of present Test Report***

General product information:

See main part of present Test Report

IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict
4.0	**GENERAL REQUIREMENTS**		P
4.2	USABILITY ENGINEERING PROCESS complies with IEC 62366 including amended definitions. Excludes production and post-production monitoring, and maintenance of the USABILITY ENGINEERING PROCESS	See attached IEC 62366 Appendix I	P
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER		P
	– established a USABILITY ENGINEERING PROCESS		P
	– established acceptance criteria for USABILITY; and		P
	– demonstrated that the acceptance criteria for USABILITY have been met.		P
5	**REPLACEMENT OF REQUIREMENTS GIVEN IN IEC 62366**		P
	The instructions for use include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY		P
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use		P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict

4	**PRINCIPLES**		**P**
4.1.1	The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT		P
4.1.2	The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met		P
4.1.3	Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS		P
4.2	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE..... :	*"Galaxy II Expediente de ingenieria de usabilidad"*	P
4.3	The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS ..... :	*"Galaxy II Expediente de ingenieria de usabilidad"*	P

5	**USABILITY ENGINEERING PROCESS**		**P**
5.1	The application of the MEDICAL DEVICE is specified in the USABILITY ENGINEERING FILE ..... :	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
	– intended medical indication		P
	– intended PATIENT population		P
	-- intended part of the body or type of tissue applied to or interacted with		P
	– intended USER PROFILE		P
	– intended conditions of use		P
	– operating principle		P
5.2	The frequently used functions that involve USER interaction with the MEDICAL DEVICE are recorded in the USABILITY ENGINEERING FILE ..... :	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
5.3.1	The MANUFACTURER identified characteristics related to SAFETY that focus on USABILITY	See Table 5.3.1	P
5.3.2	The MANUFACTURER identified known or foreseeable HAZARDS related to USABILITY	See Table 5.3.2	P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict
	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified		P
	The SEVERITY of the resulting possible HARM was determined		P
5.4	The MANUFACTURER determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY FILE	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
	The inputs to the PRIMARY OPERATING FUNCTIONS included frequently used functions and functions related to SAFETY of the MEDICAL DEVICE		P
5.5	The MANUFACTURER developed the USABILITY SPECIFICATION	See Table 5.5	P
5.6	The MANUFACTURER prepared a USABILITY VALIDATION plan	See Table 5.6	P
5.7	The MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION ..... :	See 5.8 and 5.9	—
5.8	The MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design against the requirements of the USABILITY SPECIFICATION	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
5.9	The MANUFACTURER VALIDATED USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
	If the acceptance criteria are not met and no further improvements are practicable, the medical benefits outweigh the risk	Document Reference No. in USABILITY ENGINEERING FILE: *"Galaxy II Expediente de ingenieria de usabilidad"*	P
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex K rather than the requirements of 5.1 through 5.9.	~~See Annex K below~~	N/A

6	**ACCOMPANYING DOCUMENT**		**P**
	If provided, the ACCOMPANYING DOCUMENT includes a summary of the application specification		P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict
	If provided, the ACCOMPANYING DOCUMENT includes a concise description of the ME EQUIPMENT, its operating principles and significant physical and performance characteristics, and intended USER PROFILE		P
	If provided, the ACCOMPANYING DOCUMENT is written at a level consistent with the USER PROFILE.		P
	If the ACCOMPANYING DOCUMENT is provided electronically, the USABILITY ENGINEERING PROCESS included consideration of which information also needs to be provided as hard copy or as markings on the MEDICAL DEVICE		N/A
7	**TRAINING AND MATERIALS FOR TRAINING**		**N/A**
	When training is required for the safe and effective use of PRIMARY OPERATING FUNCTIONS, the ACCOMPANYING DOCUMENT describes the available training options		**N/A**
	When training is required, the INTENDED USE and USER PROFILE(S) are the basis for training and training material		**N/A**
Annex K	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		**N/A**
K.2.1	The MANUFACTURER established an application specification as required in 5.1.	~~Document Reference No. in USABILITY ENGINEERING FILE:~~	**N/A**
K.2.2	The MANUFACTURER identified the PRIMARY OPERATING FUNCTIONS of the MEDICAL DEVICE with UOUP as required by 5.4.	~~Document Reference No. in USABILITY ENGINEERING FILE:~~	**N/A**
K.2.3	Relevant instances of USE ERROR are recorded in the USABILITY ENGINEERING FILE and addressed in K.2.4 and K.2.5.	~~Document Reference No. in USABILITY ENGINEERING FILE:~~	**N/A**
K.2.4	The MANUFACTURER reviewed the RISK ANALYSIS of the MEDICAL DEVICE with UOUP. The HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY or with PRIMARY OPERATING FUNCTIONS were identified.	~~Document Reference No. in USABILITY ENGINEERING FILE:~~	**N/A**
K.2.5	The MANUFACTURER verified that adequate RISK CONTROL measures were implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in K.2.4.	~~Document Reference No. in USABILITY ENGINEERING FILE:~~	**N/A**
	Changes to the USER INTERFACE were made to reduce RISK to an acceptable level, and those changes meet the requirements of 5.1 through 5.9.		**N/A**

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict
K.2.6	The MANUFACTURER re-evaluated the overall RESIDUAL RISK according to ISO 14971:2007, 6.4.	~~Document Reference No. in USABILITY ENGINEERING FILE or RISK MANAGEMENT FILE:~~	**N/A**
K.2.7	The ACCOMPANYING DOCUMENT of the UOUP contains an adequate summary of the application specification.		**N/A**

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.1	**USABILITY ENGINEERING FILE RESULTS TABLE: Characteristics related to SAFETY**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
An identification of characteristics related to SAFETY that focused on USABILITY was performed according to ISO 14971:2007, Clause 4.2	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
During the identification of characteristics related to SAFETY, the following was considered:			—
– application specification, including USER PROFILE(S)	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– frequently used functions			P

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
Identification of known or foreseeable HAZARDS related to USABILITY according to ISO 14971:2007, Cl. 4.3	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
The identification of HAZARDS considers HAZARDS to PATIENTS, USERS and other persons			P
Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified			P
The SEVERITY of the resulting possible HARM was determined			P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– application specification, including USER PROFILE(S)	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– task related requirements			P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– context of use	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available			P
– preliminary USE SCENARIOS			P
– possible USE ERRORS			P
– if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION			P
– results of the review of the USER INTERFACE			P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.5	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY SPECIFICATION	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
The USABILITY SPECIFICATION provides:			—
– testable requirements for USABILITY VERIFICATION	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– testable requirements for USABILITY of PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.			P
Inputs to the USABILITY SPECIFICATION include the following:			—
– application specification	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– PRIMARY OPERATING FUNCTIONS			P
– HAZARDS and HAZARDOUS SITUATIONS related to USABILITY			P
– known or foreseeable USE ERRORS associated with the MEDICAL DEVICE			P
The USABILITY SPECIFICATION describes:			—
– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– frequent USE SCENARIOS			P
– reasonably foreseeable worst case USE SCENARIOS			P
– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK			P
– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER.			P

ANNEX I - Usability engineering process checklist for IEC 60601-1-6:2010 +A1:2013			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY VALIDATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY VALIDATION plan	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
The USABILITY VALIDATION plan specifies:			—
– any method used for VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION			P
– the involvement of representative intended USERS			P
The USABILITY VALIDATION plan addresses:			—
– frequent USE SCENARIOS	*"Galaxy II Expediente de ingenieria de usabilidad"*		P
– reasonably foreseeable worst case USE SCENARIOS identified in the USABILITY SPECIFICATION			P