



LCIE



Accreditation
N°1-0312
Scope available on
www.cofrac.fr

TEST REPORT

N°: 164133-744249-C
(See report history on page 2)

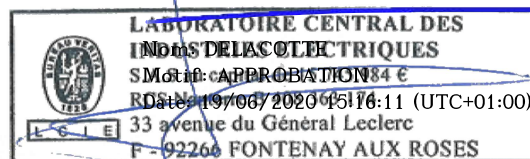
Version : 01

Subject	SAFETY TEST ACCORDING TO THE STANDARD IEC 60601-2-2: 2017
Issued to	LAMIDEY NOURY MEDICAL 3 Rue des Petits Ruisseaux ZA les Godets 91370 Verrières le Buisson FRANCE
Apparatus under test	
↳ Product	High frequency surgical equipment
↳ Trade mark	LAMIDEY NOURY MEDICAL
↳ Manufacturer	LAMIDEY NOURY MEDICAL
↳ Model under test	V10GMS -- ELECTROSURGICAL UNIT SEAL V10GOPT4 -- ELECTROSURGICAL UNIT OPTIMA
↳ Serial number	--
Conclusion	Compliant
Test date	February 10 th , 2020 to May 29 th , 2020
Test location	Fontenay Aux Roses
Composition of document	49 pages
Document issued on	June 3 rd , 2020

Written by :
Damien AIRAULT
Tests operator

Nom: LAGOS
Motif: VERIFICATION
Date: 19/06/2020 15:17:15 (UTC+01:00)

Approved by :
Rodolphe DA SILVA
Technical manager



This document shall not be reproduced, except in full, without the written approval of the LCIE. This document contains results related only to the items tested. It does not imply the conformity of the whole production to the items tested. Unless otherwise specified or rule defined by the test method, the decision of conformity doesn't take into account the uncertainty of measures. This document doesn't anticipate any certification decision. The COFRAC accreditation attests the technical capability of the testing laboratory for the only tests covered by the accreditation. If some tests mentioned in this report are carried out outside the framework of COFRAC accreditation, they are indicated by an asterisk (*).

LCIE
Laboratoire Central des Industries Electriques
Une société de Bureau Veritas

33, Av du Général Leclerc
92266 Fontenay Aux Roses
FRANCE

Tél : +33 1 40 95 60 60
contact@lcie.fr
www.lcie.fr



PUBLICATION HISTORY

Each new edition of this test report replaces and cancels the previous edition. The control of the old editions of report is under responsibility of client.

VERSION	PAGES MODIFIED	DESCRIPTION OF CHANGES	CHANGE REQUEST BY	APPROVAL DATE
01	—	Test report No 164133-744249-C Original version	—	June 3 rd , 2020

CONCLUSION

**The tested equipment complies with the requirements of the standard
IEC 60601-2-2: 2017**

Test Report issued under the responsibility of:



TEST REPORT IEC 60601-2-2 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	
Report Number.....	164133-744249-C Version 01
Date of issue.....	June 3 rd , 2020
Total number of pages	49 (including the two cover pages)
Name of Testing Laboratory preparing the Report	LCIE 33, Avenue du Général Leclerc 92260 Fontenay-Aux-Roses — FRANCE
Applicant's name	LAMIDEY NOURY MEDICAL
Address.....	3 Rue des Petits Ruisseaux ZA les Godets 91370 Verrières le Buisson -- FRANCE
Test specification:	
Standard	IEC 60601-2-2: 2017 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 or IEC 60601-1:2012
Test procedure	N/A
Non-standard test method	N/A
Test Report Form No.	IEC60601_2_2G
Test Report Form(s) Originator	UL(US)
Master TRF	2017-07-21
Copyright © 2017 IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System). All rights reserved.	
This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.	
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.	



LCIE

Test item description :	High frequency surgical equipment	
Trade Mark :	LAMIDEY NOURY MEDICAL	
Manufacturer	LAMIDEY NOURY MEDICAL	
Model/Type reference	V10GMS -- ELECTROSURGICAL UNIT SEAL V10GOPT4 -- ELECTROSURGICAL UNIT OPTIMA	
Ratings :	110-120V~ ; 50/60Hz or 220-240V~ ; 50/60Hz 1200 VA ; Type CF ; Class I	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	Testing Laboratory:	LCIE
Testing location/ address :	33, Avenue du Général Leclerc 92260 Fontenay-Aux-Roses — FRANCE	
Tested by (name, function, signature) :	Damien AIRAULT Test Engineer	
Approved by (name, function, signature) ... :	Rodolphe DA SILVA Technical Manager	



List of Attachments (including a total number of pages in each attachment):		
None		
Summary of testing:		
Tests performed (name of test and test clause):		Testing location:
201.8.4.101	NEUTRAL ELECTRODE monitoring circuit	LCIE 33, Avenue du Général Leclerc 92260 Fontenay-Aux- Roses FRANCE
201.8.4.102	Neuromuscular stimulation	
201.8.7.3.101	Thermal Effects of HF LEAKAGE CURRENTS	
201.8.7.3.101a	Monopolar & Bipolar	
201.8.7.3.101c	Cross-coupling	
201.11.6.3	Spillage on ME EQUIPMENT	
201.11.8	Interruption of the power supply	
201.12.1	Output power	
201.12.1.101a	Output power accuracy monopolar output Fig. 201.109	
201.12.1.101b	Output power accuracy bipolar output Fig. 201.110	
201.12.1.102a	Output power monotonicity monopolar output Fig. 201.109	
201.12.1.102b	Output power monotonicity bipolar output Fig. 201.110	
201.12.4.2.101	Output indicator	
201.12.4.4.101	Maximum allowed output power in SINGLE FAULT CONDITIONS	
Summary of compliance with National Differences (List of countries addressed):		
<ul style="list-style-type: none"> List of countries addressed to IEC 60601-2-2: 2017 (for explanation of codes see below): None National Differences for : -- <p>The text of the International Standard IEC 60601-2-2: 2017 was approved by CENELEC as a European Standard without any modification.</p> <ul style="list-style-type: none"> List of countries addressed to EN 60601-2-2: 2018 (for explanation of codes see below): AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, TR <p><u>Code explanation :</u> AE=United Arab Emirates, AR=Argentina, AU=Australia, AT=Austria, BH=Bahrain, BY=Belarus, BE=Belgium, BR=Brazil, BG=Bulgaria, CA=Canada, CH=Switzerland, CN=China, CO=Colombia, CY=Cyprus, CZ=Czech Republic, DE=Germany, DK=Denmark, EE=Estonia, ES=Spain, FI=Finland, FR=France, GB=United Kingdom, GR=Greece, HR=Croatia, HU=Hungary, IE=Ireland, IN=India, IS=Iceland, IL=Israel, IT=Italy, JP=Japan, KE=Kenya, KR= Korea, KZ=Kazakhstan, LT=Lithuania, LU=Luxembourg, LV=Latvia, MK= Former Yugoslav Republic of Macedonia, MT= Malta, MX=Mexico, MY=Malaysia, NL=The Netherlands, NO=Norway, NZ=New Zealand, PK=Pakistan, PL=Poland, PT=Portugal, RO=Romania, RU=Russia, SA=Saudi Arabia, SE=Sweden, SG=Singapore, SI=Slovenia, S</p>		
<input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-2-2: 2017		