



HERMON LABORATORIES

CERTIFICATE

CERTIFICATE OF CONFORMITY

With EN 60601-1: 2006 + A11:2011 + A1:2013; IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint); ANSI/AAMI ES60601-1:2005/(R):2012 +A1:2012+ C1:2009+ A2:2010; CAN/CSA-C22.2 No. 60601-1:14 standards

Certificate Number NOVSAF_EN.38919C_rev2

This certificate of conformity has been granted to the applicant based on the results of tests and evaluations, performed by Hermon Laboratories from 25 December, 2018 to 6 October, 2019 and 23 July, 2020 on representative sample of the specified product.

Product description

Tested item: Cancer Treatment Device in Torso area
Models: Optune Lua (NovoTTF-200T), model: TFT9200
Serial number: 001
Hardware version: TFT1200_BOM_NVC A01
Software release: 40.1.10.1

Applicant details

Name: NovoCure Ltd.
Address: Topaz Building, MATAM Center, Haifa 3190500, Israel

Manufacturer details

Name: NovoCure GmbH
Address: Park 6 / Platz 10, 8039 Root D4, Switzerland

This is to certify that the tested product sample satisfies the requirements of the above listed standard/s.

Measurement/test results are contained in the test report: NOVSAF_EN.38919_rev2.
The comments in the associated test report shall be taken into account and used in conjunction with this certificate

Michael Brun,
Product Safety Group Manager
Hermon Laboratories Ltd.

December 10, 2020

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EXPERTS IN GLOBAL COMPLIANCE SOLUTIONS



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Approvals

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