

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 731459 R000

Manufacturer: Philips Image Guided Therapy Corporation

Address:

9965 Federal Drive
Colorado Springs
Colorado
80921
USA

Single Registration Number: US-MF-000018632

EU Authorised Representative: Philips Medical Systems Nederland B.V.

Address:

Veenpluis 6
5684PC Best
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-11-04**

Current Issue Date: **2023-02-20**

Starting Validity Date: **2023-02-20**

Expiry Date: **2026-11-03**

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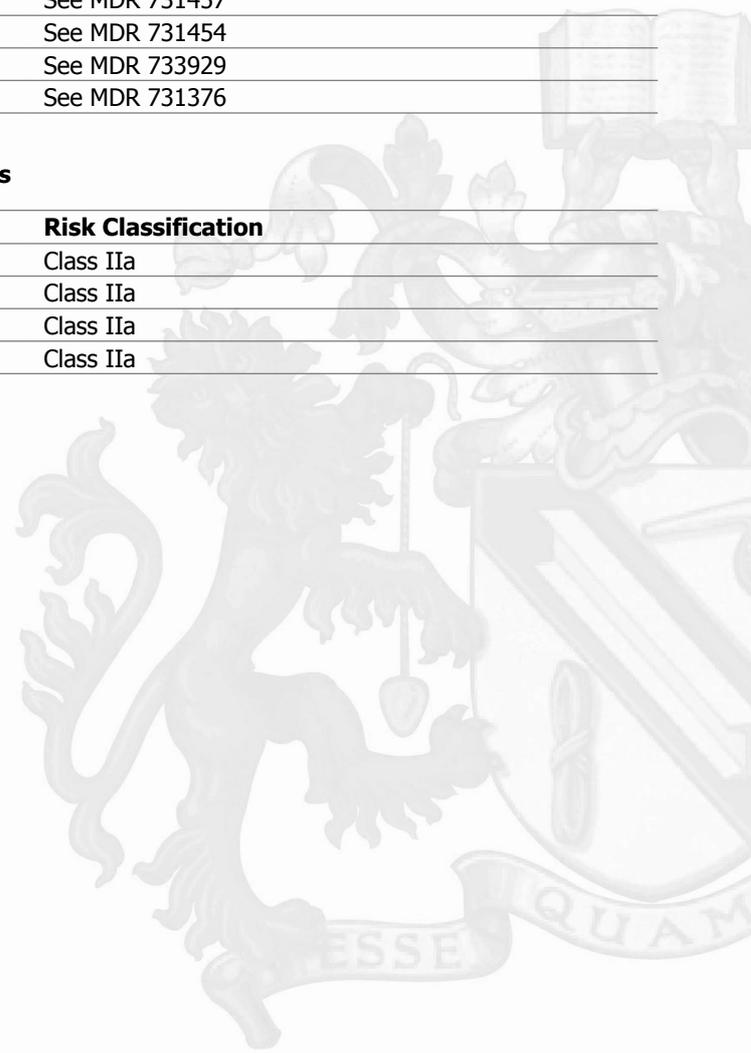
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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
AngioSculpt EVO RX PTCA Scoring Balloon Catheter	See MDR 731457
Stellarex 0.035" OTW Drug-coated Angioplasty Balloon	See MDR 731454
Refinity ST Rotational IVUS Catheter	See MDR 733929
Bridge Occlusion Balloon Catheter	See MDR 731376

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Image Acquisition and Processing Systems	Class IIa
Peripheral Catheters	Class IIa
Lead Locking Device (LLD) Lead Removal Devices and Accessories	Class IIa
Peripheral Intravascular Ultrasound Catheters	Class IIa



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-04	3249968	Issued
2022-01-12	3598092	Amended – Addition of subcontractor Volcano Corporation (San Diego, CA, USA) and removal of subcontractor Volcano Corporation (Rancho Cordova, CA, USA).
2022-04-26	3623393	Supplemented – Addition of LLD Lead Removal devices. Amended – Addition of manufacturer SRN.
2022-05-26	3640626	Amended – Addition of subcontractor and crucial supplier: Philips IGTC (Plymouth, MN) and Indena S.p.A. Supplemented – Addition of Stellarex 0.035” OTW Drug-coated Angioplasty Balloon devices.
2022-08-31	3736104	Amended - Change of subcontractor name from “Creganna Medical Pte Limited” to “Quasar Medical (Singapore) Pte Ltd.”
Current	3789765	Supplemented – Addition of Refinity ST Rotational IVUS Catheter and Bridge Occlusion Balloon Catheter devices. Addition of device category Peripheral Intravascular Ultrasound Catheters.

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