

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 790895 R000

Manufacturer: Transonic Systems Inc.

Address:

34 Dutch Mill Road
Ithaca
New York
14850
USA

Single Registration Number: US-MF-000008784

EU Authorised Representative: Transonic Europe B. V

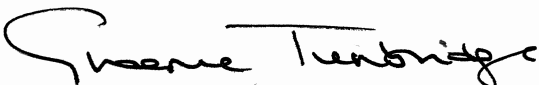
Address:

Business Park Stein 205
6181 MB Elsloo
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Global Regulatory & Quality

First Issue Date: **2026-04-21**

Current Issue Date: **2026-04-21**

Starting Validity Date: **2026-04-21**

Expiry Date: **2031-04-20**

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Page 1 of 4

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

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Device Schedule:

Intended Purpose as per the Instructions for Use:

Transonic’s FlowXL and Optima/AureFlo Flowprobes use transit-time ultrasound technology to measure volume flow of blood and other liquids, and report derived parameters such as but not limited to Pulsatility Index, Diastolic Filling Percentage, and Diastolic/Systolic Ratio during surgical interventions.

Risk Classification: Class III

Basic UDI-DI: 087746600HQHSPRLX

Device Name	Model	Type (Codes as per (EU) 2017/2185)
HS-Series Flowprobes, compatible with FlowXL Flowmeters	Coronary Flowprobes, Reusable - HSnFMC-75 (n=1.5, 2, 3, 4); Vascular Flowprobes, Reusable - HSnFMV-75 (n=1.5, 2, 3, 4, 6, 8, 10, 12, 14); Carotid Flowprobes, Reusable - HSnFME-75 (n=1.5, 2, 3, 4, 6, 8, 10); Microvascular Flowprobes, Reusable - HSnMU-50 (n=0.7, 1, 1.5, 2, 3); Cerebrovascular Flowprobes, Long-Handle, Reusable - HSnMR-16 (n=1.5, 2, 3); Cerebrovascular Flowprobes, Short-handle, Reusable - HSnMRS-16 (n= 3, 4, 6); Cerebrovascular Flowprobes, Long-Handle Single Use - HSnMB-01 (n=1.5, 2, 3); Cerebrovascular Flowprobes, Short-handle, Single Use - HSnMBS-01 (n= 3, 4, 6); COncidence Ultrafit Liners (Sold in 5 pack) - HnAUL-5 (n=4, 6, 8, 10,12, 14, 16, 20, 24, 28, 32, 36); COncidence Flowprobes, 8 use - HSnAU-08 (n=4, 6); COncidence Flowprobes, 75 use - HSnAU-75 (n=8,10,12,14, 16, 20, 24, 28. 32, 36).	MDA 0202

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Page 2 of 4

Validity of this certificate is conditional on the Manufacturer’s quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 790895 R000

Device Name	Model	Type (Codes as per (EU) 2017/2185)
HQE/F/G Flowprobes, compatible with Optima & AureFlo Flowmeters	Coronary Flowprobes, Reusable – HQFnFMC (n=1.5, 2, 3, 4); Vascular Flowprobes, Reusable – HQFnFMV (n=1.5, 2, 3, 4, 6, 8, 10, 12, 14); Carotid Flowprobes, Reusable – HQFnFME (n=1.5, 2, 3, 4, 6, 8, 10); Microvascular Flowprobes, Reusable – HQFnMU (n=0.7, 1, 1.5, 2, 3); Cerebrovascular Flowprobes, Long-Handle, Reusable – HQEnMR (n=1.5, 2, 3); Cerebrovascular Flowprobes, Short-Handle, Reusable - HQEnMR-S (n= 3, 4, 6); Cerebrovascular Flowprobes, Long-Handle, Single Use – HQGnMB (n=1.5, 2, 3); Cerebrovascular Flowprobes, Short-Handle, Single Use - HQGnMB-S (n= 3, 4, 6); COncidence Flowprobes, Limited Use – HQEnAU (n=4, 6); COncidence Flowprobes, Reusable – HQFnAU (n=8,10,12,14,16,20,24,28,32,36); COncidence Ultrafit Liners (Sold in pack of 5) - HnAUL-5 (n=4,6,8,10,12,14,16,20,24,28,32,36).	MDA 0202

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Page 3 of 4

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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
Current	3807692	Issued



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