

**Business Stream Products
Certification Department**



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Joseph Sbrogna
TechDevice LLC
650 Pleasant St.
WATERTOWN MA 02472
USA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 06, 2018

Application for : QMS
Certificate No. : SX 60125805 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

Dear Mr. Sbrogna,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60125805 0001.

Kind regards

Certification body

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

TechDevice LLC
650 Pleasant St.
Watertown MA 02472
USA

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development and Manufacture of Guidewires,
Balloon Dilatation Catheters and Latex Balloon Catheters**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-05
Certificate Registration No.: SX 60125805 0001
An audit was performed. Report No.: 31692907 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2018-01-05



M. Aihara
M.Sc. M. Aihara

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