

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Tsukada Medical Research Co., Ltd.
1931-1 Motohara Sanada-machi
Ueda-city, Nagano 386-2202
Japan

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

Design and Development, Manufacture and Distribution of
Infusion instruments, Urologic catheter, Catheter plug,
Gastrostomy catheters and Sinus catheter

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: 2017-10-02
Certificate Registration No.: SX 60123685 0001
An audit was performed. Report No.: 12031362 001
This Certificate is valid until: 2018-12-03

Certification Body



Date 2017-10-02



M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>