

# Declaration of Conformity

Manufacturer: **Nemoto Kyorindo Co., Ltd.**

2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

Authorized European Representative:

**Medicor International NV**

Wingepark 5B-101 3110 Rotselaar Belgium

Product: **CT Contrast Delivery Systems DUAL SHOT alpha7**

Valid from: Starting from serial number QCB30367G/QCU30016G/QCBS3146G,  
and in conjunction with the release documents for the product.

**We herewith declare that the above mentioned device meets all applicable provisions of the EC Directive 93/42/EEC.**

**The following Standards were applied:**

EN ISO 13485:2016	Medical devices-Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN 60601-1:2006+A1:2013	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006	Medical device software – Software life-cycle processes
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied –Part 1 : General requirements

Conformity Assessment Procedure:

**Annex II (exclude Sec. 4) of the EC Directive 93/42/EEC.**

Notified Body: **TÜV Rheinland LGA Products GmbH CE 0197**

Registration No.: **HD 60134044 0001**

Classification: **I Ib according to Annex IX of MDD, Rule 11, Sub-clause 1, Indent 1**



Place: **Tokyo, Japan**

Date: **February 18, 2019**

*Makoto Yasuda*

**Makoto Yasuda**  
General Manager