Issue No. 100-00263-04

Declaration of Conformity

(Medical Device Directive 93/42/EEC)

Manufacturer : Hadeco, Inc.
Address : 2-7-11 Arima, Miyamae-ku, Kawasaki, 216-0003, Japan

European Authorized Representative
: ICHIYAMA GmbH
Address : Benderstraße 130, 40625 Düsseldorf, Germany

Herewith declares that
Product : Smartdop XT
Type design : Class IIa
Product: Smartdop XT, Classification: Class IIa rule10
Option: Probe Classification: Class IIa rule10
(BT4M05S8C(A),BT5M05S8C(A),BT8M05S8C(A),
BP8M05S8A,BF8M15S8A,PG-01)

Rating / characteristics : Ultrasonic Doppler blood flow meter

is in conformity with provisions of the Medical Device Directive 93/42/EEC Annex ll exclusive (4) latest amended by 2007/47/EC.
Hadeco is exclusively responsible for the declaration of conformity.

and furthermore declares that
Harmonized standards :
Refer "100-00208 Smartdop XT Applicable standards for essential requirements"

Technical file : Technical file for Smartdop XT
The validity period of the declaration of conformity :
2024/05/26 (CE Certificate: 0123/MDD/ G1 093084 0004 Rev.00)

Notified body : TÜV SÜD Product Service GmbH CE 0123
Zertifizierstellen, Ridlerstraße 65, 80339 MÜNCHEN, Germany

Japan, 2020/03/11

Yutaka Wakasu : Quality Control Director