Issue No. 100-00309-03

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 : Bidop ES-100V3
Type design : Class IIa
Product: Bidop ES-100V3, Classification: Class IIa rule10
Option: Probe Classification: Class IIa rule10
(BT2M20S8C(A), BT4M05S8C(A), BT5M05S8C(A), BT8M05S8C(A), BT10M5S8C(A), BF2M20S8A, BF8M15S8A, PG-21)
Option: Probe Classification: Class IIa rule6
(VRP-08, VRP-10, VRP-20, LRP-08, LRP-10, FDP-08, ACP-08)

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 "040-02409 Applicable standards for essential requirements"

Technical file : Technical file for Bidop ES-100V3
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

Yutaka Wakasu : Quality Control Director