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 7
Type design : Class IIa
Product: Bidop 7, Classification: Class IIa rule10
Option: Probe Classification: Class IIa rule10
(ST2M25S8C(A), ST4M05S8C(A), ST5M05S8C(A), ST8M05S8C(A), ST10M5S8C(A), SF8M15S8A, PG-30)
Option: Probe Classification: Class IIa rule6
(VRP-08, VRP-10, 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 II exclusive (4) latest amended by 2007/47/EC.
Hadeco is exclusively responsible for the declaration of conformity.

and furthermore declares that
Harmonized standards :
Refer "100-00415 Bidop 7 applicable standards for essential requirement"

Technical file : Technical file for Bidop 7
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, 2020/03/05

Yutaka Wakasu : Quality Control Director