Issue No. 040-00199-11

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 : ES-100VX
Type design : Class IIa
Product: ES-100VX, Classification: Class IIa rule10
Option: Probe Classification: Class IIa rule10
(BT2M20S8C(A), BT4M05S8C(A), BT5M05S8C(A), BT8M05S8C(A), BT10M5S8C(A), BP8M05S8A, BP10M05S8A, BF2M20S8A, BF8M15S8A)
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 detector

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 "040-00156 Applicable standards for essential requirement"

Technical file: Technical file for ES-100VX
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