ZERTIFIKAT · CERTIFICATE · 認証書 · СЕРТИФИКАТ · CERTIFICADO · CERTIFICAT

EC Certificate

No.: G1 03 12 43398 024

Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

The Certification Body of TÜV PRODUCT SERVICE certifies that

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku
Osaka 531-8510
Japan

with the authorized EC representative:

Nipro Europe N.V.
Weihoek 3H
B-1930 Zaventem
Belgium

in the facility(ies)

- **Nipro Corporation Odate Factory**
  8-7, Hanukiyachi, Niida
  Odate-shi, Akita 018-5794
  Japan

for the product(s)/product category(ies)

Hemodialyzers, Hemofilters, AV Fistula Needles, Plasma Separators, Balloon Infusers, Platelet Bags, Endotoxin Filter, Huber Needles / Huber Needle Sets, Intravenous Catheters, Stopcocks

maintains a quality system which ensures that the products conform with the essential requirements of the Directive, which apply to them at every stage from design to final controls.

Reasoned assessment see audit report no.: TYOMQS17394A

Provided the agreed periodical surveillance is carried out, this certificate is valid until 2006-11-05.

Released with the above mentioned certificate number by the Certification Body of TÜV PRODUCT SERVICE.

Department: TYOMED / ts-kym
Date: 2003-12-19

TÜV PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42//EEC concerning medical devices with identification no. 0123.

TÜV PRODUCT SERVICE GMBH
Zertifizierstelle
Ridlerstraße 65 D-80339 München
Gruppe TÜV Süddeutschland

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

vertreten im
ZLG-ZQ-998.98.12-48