EC Declaration of Conformity

EG-Konformitätserklärung

We

Wir

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
D-34212 Melsungen

hereby declare in our own responsibility that the product/s

Diapact® CRRT

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

The product/s is/are covered by

EC Certificate No. G1 03 02 21273 025

issued by:

TÜV Product Service GmbH

as notified body according to Council directive 93/42/EEC concerning medical devices with identification no. 0123.

The product/s are class IIb medical devices according to rule 11 of MDD 93/42/EEC Annex IX.

Validity of this declaration: 1 year

The list of product article numbers is provided in the attachment of this declaration.

erklären in eigener Verantwortung, dass das/die Produkt/e

Diapact® CRRT

mit den folgenden Richtlinien/Gesetzen/Normen übereinstimmt/en

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

Das/die Produkt/e sind enthalten in

EG-Zertifikat Nr. G1 03 02 21273 025

ausgestellt von:

TÜV Product Service GmbH

als Benannte Stelle entsprechend der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte mit der Identifikationsnr. 0123.

Das/die Produkt/e ist/sind Medizinprodukte der Klasse IIb gemäß Regel 11 MDD 93/42/EWG Anhang IX.

Gültigkeit dieser Erklärung: 1 Jahr

Eine Liste der Artikelnummern des/der oben genannten Produkte/s ist dieser Erklärung angehängt.

Dr. Wolfgang Feller
Managing Director

Melsungen, 22/06/2004

Dr. Giuliana Gavioli
Head of Division RA

Mirandola, 22/06/2004

Birgit Unger
Head of Division QM
i.V.

Melsungen, 22/06/2004

article number	article name
7106505	Diapact® CRRT
7106510	Diapact® CRRT (120 V Version)
7106506	Option CN-Plug
7102505	Option Perfusor Interface

Dr. Wolfgang Feller
Managing Director

Dr. Giuliana Gavioli
Head of Division RA

Birgit Unger
Head of Division QM
i.V.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 05 02 21273 035

Manufacturer:

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

Product Category(ies):

Active medical devices for extracorporeal blood treatment: haemodialysis, acute dialysis, plasmapheresis

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 70092089

Valid until: 2010-03-02

Date, 2005-03-03

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 · TÜV SÜD Gruppe · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany