Declaration of Conformity for Medical Devices

according to COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993 concerning medical devices

Manufacturer	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany
Product Group	Original-Infusomat®-Tubings, Infusomat® Space Lines
Conformity Assessment Procedure	according to ANNEX II.3 of the COUNCIL DIRECTIVE
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE Klasse IIa
Notified Body	TÜV Product Service GmbH Ridlerstrasse 65 80339 München Germany Identification number 0123
Date of first CE-marking	Original-Infusomat®-Tubings 1994-12 Infusomat® Space Lines 2004-07

We herewith declare that the above mentioned product group meets all requirements of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices which apply to it.

Melsungen, 2004-07-23

B. Braun Melsungen AG

i. V.
J. Heil
Quality Management

i. V.
R. Ebert
Strategic Marketing

i. A.
B. Schacht
Research & Development

Declaration of Conformity for Medical Devices

according to COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993 concerning medical devices

Manufacturer	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany
Product Group	B. Braun Space Active Infusion System for Fluid Management (see attachment)
Conformity Assessment Procedure	according to ANNEX II.3 of the COUNCIL DIRECTIVE
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE class IIb
Notified Body	TÜV Product Service GmbH Ridlerstrasse 65 80339 München Germany Identification number 0123
Date of first CE-marking	2004-06

We herewith declare that the above mentioned product group meets the Essential Requirements of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.

Melsungen, 2004-06-02

B. Braun Melsungen AG

i. V.

J. Heil
Quality Management

i. V.

M. Lauer
Research & Development

Attachment to

Declaration of Conformity for Medical Devices

dated 2004-06-02

B. Braun Space
Active Infusion System for Fluid Management

Main components	Article number
Perfusor® Space Infusion Syringe Pump	8713030
B. Braun Space Station	8713140
B. Braun Space Cover comfort	8713145
B. Braun Space Cover standard	8713147

Accessories

B. Braun Pole Clamp SP	8713130
Plug-in Power Supply SP (UK Plug)	8713111
Plug-in Power Supply SP (Euro Plug)	8713110
Plug-in Power Supply SP (US Plug)	8713112
Plug-in Power Supply SP (Australian Plug)	8713113
Combi Lead 12 V	8713133
Battery-Pack SP (NiMH)	8713180
Extension Lead SP 60 cm	8713210
Extension Lead SP 120 cm	8713215
Connection Lead SP (12 V)	8713231
Connection Lead for Staff Call SP	8713232
Interface Lead RS232 SP	8713234

EC-Certificate

No. G1 03 12 12974 032

Holder of Certificate: **B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
Germany

Product Category: **Sterile Disposable Medical Devices for Infusion, Transfusion and Vene Puncture; Epidural and Spinal Needles; Hypodermic Needles and Pen Cannulae**

This EC Certificate is issued according to Annex II.3 of Council Directive 93/42/EEC concerning medical devices. The Certification Body of TÜV PRODUCT SERVICE certifies that the certificate holder 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. Validity of this EC Certificate requires periodical surveillance. See also notes overleaf.

Report no.:	70058993
Valid until:	2005-07-05

Date, 2003-12-10

TÜV PRODUCT SERVICE 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

EC-Certificate

No. G1 03 06 12974 019

Holder of Certificate: **B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
Germany

Product Category: **Active Medical Devices for fluid management physiological monitoring systems**

This EC Certificate is issued according to Annex II.3 of Council Directive 93/42/EEC concerning medical devices. The Certification Body of TÜV PRODUCT SERVICE certifies that the certificate holder 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. Validity of this EC Certificate requires periodical surveillance. See also notes overleaf.

Report no.: 70043512

Valid until: 2005-03-11

144581

Date, 2003-07-23

TÜV PRODUCT SERVICE 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

EC-Certificate

No. G1 03 10 12974 027

Holder of Certificate: **B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
Germany

Product Category: **Sterile Medical Devices for**
- Fluid Management including ECG-Cables
- Autotransfusion
- Suction
- Wound Drainage
- Artificial Nutrition
- Catheterization
as well as related sets manufactured on customer order

This EC Certificate is issued according to Annex II.3 of Council Directive 93/42/EEC concerning medical devices. The Certification Body of TÜV PRODUCT SERVICE certifies that the certificate holder 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. Validity of this EC Certificate requires periodical surveillance. See also notes overleaf.

Report no.: 70054615

Valid until: 2008-09-26

Date, 2003-10-27

TÜV PRODUCT SERVICE 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

Product Service

TÜV Product Service GmbH • Ridlerstraße 65 • 80339 München • Deutschland

Competence.
Certainty.
Quality.

B. Braun Melsungen AG
Frau Susanne Kaltenbach
Carl-Braun-Str. 1

34212 Melsungen

Ihre Zeichen/Nachricht vom	Unsere Zeichen/Name	Tel.-Durchwahl/E-Mail	Fax-Durchwahl	Datum	Seite
	MHS2-du Elga Dussmann	089 / 50 08 - 41 61 Elga.Dussmann@tuev-sued.de	089 / 50 08 - 42 87	29.11.2004	1 von 1

CE Certificate G1 02 08 12974 250

To whom it may concern

TÜV PRODUCT SERVICE GMBH confirms that the request for extension of the CE Certificate G1 02 08 12974 250 (product scope: "Medical Devices for Infusion and Transfusion Equipment, Anaesthesia, Vein Puncture, Urology, Biopsy, Endoscopy, and Sets manufactured on customer order") is currently in process. A new certificate according to MDD 93/42/EEC Annex II.3 will be issued after successful approval and release by our certification board.

Best regards,

TÜV Product Service GmbH

i.A. Jürgen Kunte
Nicht-Aktive Medizinprodukte

i.A. Elga Dussmann
Nicht-Aktive Medizinprodukte

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

EC Certificate

No.: G1 02 08 12974 250

TÜV PRODUCT SERVICE

Decision according to Annex II, Clause 3 of Council Directive No. 93/42/EEC concerning medical devices.

The Certification Body of TÜV PRODUCT SERVICE certifies that

B. Braun Melsungen AG

Carl-Braun-Str. 1

34212 Melsungen

in the facility(ies)

- B. Braun Melsungen AG / Sparte Medical, Carl-Braun-Str. 1, D-34212 Melsungen (Design)
- Werke A und K: Carl-Braun-Str. 1, D-34212 Melsungen (Manufacturing)
- Werk E: Schwarzenberger Weg 21-27, D -34212 Melsungen (Manufacturing)
- Werk P: Werksanlage Pfieffewiesen, D -34212 Melsungen (Manufacturing)
- Werk Spangenberg: Dörnbach, D-34286 Spangenberg (Manufacturing)

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

Medical Devices for Infusion and Transfusion Equipment, Anaesthesia, Vene Puncture, Urology, Biopsy, Endoscopy, and Sets manufactured on customer order

maintains a quality system which ensures that the product(s) conform(s) 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.: 70027085.

Provided the agreed periodical surveillance is carried out, this certificate is valid until 11-16-2004.

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

Department: MUCMED2 / ku-f
Date: 28-Aug-2002

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