

Certificate

Production Quality Assurance System Approval Annex V of the Directive on Medical Devices

ECM, Eifelstr. 1c, 52068 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Impromediform GmbH

Gielster Stück 11, 58513 Lüdenscheid

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

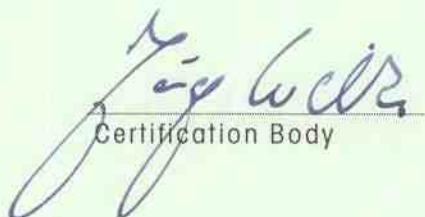
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Date of initial certification: 2003-12-17

Prolongation: 2008-12-17

Report Number	Registered under	Valid until
179-08-214	Z/08/01742	2013-12-17

Aachen, 2008-12-17


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08

Annex I to Certificate Z/08/01742

Number of Pages: 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use device	Intravenous Administration Sets, General-Purpose	16-649

Special terms of validity:

None.

¹ UMDNS Code is optional