

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 574436**
Issued To: **Humares GmbH**
Im Schollengarten 24
76646 Bruchsal
Germany

In respect of:

Manufacture of sterile single-use autohemotherapy sets, single-use photobiological autohemotherapy sets, and disposable accessories for extracorporeal UV autohemotherapy.

Herstellung von sterilen Einweg-Autohemotherapy-Sets, Einweg-photobiologische autohemotherapy-Sets und Einweg-Zubehör für die extrakorporale UV-Autohemotherapy.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 June 2016**

Date: **27 February 2017**

Expiry Date: **14 February 2022**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 574436**
Date: **27 February 2017**
Issued To: **Humares GmbH
Im Schollengarten 24
76646 Bruchsal
Germany**

Subcontractor:	Service(s) supplied
AKAtech Produktions- und Handels GmbH Member of CCS Group Untermühlberg 1 4890 Frankenmarkt Austria	Manufacture
EUMATRON GmbH Reichenhaller Straße 48 81547 München Germany	Manufacture
Fresenius Kabi AG Else-Kröner-Straße 1 61346 Bad Homburg Germany	Manufacture
PMT Präzision-Medizin-Technik GmbH Im Gewerbegebiet 11 66709 Weiskirchen Germany	Manufacture

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76646 Bruchsal
Germany**

Subcontractor:

Service(s) supplied

Rose Medizin- und
Sterilisiertechnik GmbH
Gottbillstrasse 25-30
54294 Trier
Germany

Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 574436**
Date: **27 February 2017**
Issued To: **Humares GmbH
Im Schollengarten 24
76646 Bruchsal
Germany**

Date	Reference Number	Action
23 June 2016	8533895	First issue. Transfer from another Notified Body.
27 February 2017	8690497	Renewal and Changes to German text, addition subcontractor PMT.

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