

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 574438**
Issued To: **Humares GmbH**
Im Schollengarten 24
76646 Bruchsal
Germany

In respect of:

Design and manufacture of colon therapy and ozone therapy devices.

Design und Herstellung von Produkten für Colonthérapie und Ozontherapie.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 574438**
 Date: **27 February 2017**
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Date	Reference Number	Action
23 June 2016	8533895	First issue. Transfer from another Notified Body.
27 February 2017	8690498	Renewal and removal of oxygen partial measurement devices from scope, correction to wording, removal of subcontractor PMT.

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