By Royal Charter

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 Colontherapie 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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EC Certificate - Full Quality Assurance System Certificate History

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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.