

EC Certificate - Full Quality Assurance System

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

No.**CE 687568****Issued To:**

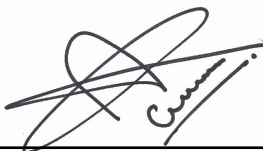
**Chalice Medical Limited
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom**

In respect of:

Design and manufacture of water heater / cooler for use during extracorporeal bypass procedures

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2018-06-01**

Date: **2019-02-06**

Expiry Date: **2021-08-03**

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

List of Significant Subcontractors

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

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 Date: **2019-02-06**
 Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
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Subcontractor:

Service(s) supplied

Hirtz & Co
 Bonner Strasse 180
 Köln
 50968
 Germany

Manufacture

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Certificate History

Certificate No: **CE 687568**
Date: **2019-02-06**
Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
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United Kingdom

Date	Reference Number	Action
01 June 2018	8883028	First Issue, Transfer from another Notified Body.
Current	8940655	Traceable to NB 0086.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.