

State of Minnesota

SECRETARY OF STATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This Public Document: EC Certificate – Full Quality Assurance System

2. has been signed by Darlene R Berthon

3. acting in the capacity of Notary Public, State of Minnesota

4. bears the seal/stamp of Darlene R Berthon, Notary Public, State of Minnesota

CERTIFIED

5. at: St. Paul, Minnesota

6. Date: March 9, 2015

7. by: Secretary of State, State of Minnesota

8. File No: 8159190-1

9. Seal/Stamp:

10. Signature:



A handwritten signature in cursive script that reads "Steve Simon".

Steve Simon
Secretary of State



EC Certificate - Full Quality Assurance System

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

I hereby certify that this is an
original copy of the document
held at Bayer Medical Care Inc.

No.

Issued To:

CE 631845

**Bayer Medical Care Inc.
Also doing business as Medrad, Inc.
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA**



Darlene Berton 3-6-15

In respect of:

The design, development and manufacture of minimally invasive tissue and thrombus removal devices.

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):

Pietro Foschi - Strategic Delivery Director

First Issued: **04 March 2015**

Date: **04 March 2015**

Expiry Date: **20 March 2020**

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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

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:

Certificate No: **CE 631845**
 Date: **04 March 2015**
 Issued To: **Bayer Medical Care Inc.**
Also doing business as Medrad, Inc.
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA

Subcontractor:	Service(s) supplied
Bayer Medical Care Inc. 625 Alpha Drive Pittsburgh Pennsylvania 15238 USA	Manufacture
Bayer Medical Care Inc. 8880 Evergreen Blvd. NW Minneapolis Minnesota 55433 USA	Design Manufacture
Bayer Medical Care Inc. 9055 Evergreen Blvd, NW Minneapolis Minnesota 55433 USA	Manufacture
Bayer Medical Care, B.V. Horsterweg 24 6199 AC Maastricht Airport Netherlands	EU Representative

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USA

Subcontractor:	Service(s) supplied
Minnetronix, Inc. 1635 Energy Park Drive St. Paul Minnesota 55108 USA	Manufacture Testing
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 631845**
 Date: **04 March 2015**
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Also doing business as Medrad, Inc.
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA

Date	Reference Number	Action
04 March 2015	8291132	First issue. Transfer of products from CE 543532.

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