

Certificate of CE-Registration



mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

as stipulated and demanded by the aforementioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.
Microsurgical Instruments	15-621 – Class I	DE/CA09/0760/100
Inserters, Intraocular Lens	17-544 – Class I	DE/CA09/0760/240
Inserters	17-543 – Class I	DE/CA09/0760/491
Cataract Extraction Units, Phacoemulsification	17-596 – Class I	DE/CA09/0760/1104-Ä1
Markers	12-440 – Class I	DE/CA09/0760/1105
Positioning Aids	16-223 – Class I	DE/CA09/0170/1106
Eye Cannula	10-573 – Class IIa	DE/CA09/0760/1232

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

April 2014

Werner Sander
President & CEO

Declaration of Conformity Certificate

We **ASICO LLC**
26 Plaza Drive
Westmont
IL 60559
USA

Declare with sole responsibility, that our product/s:

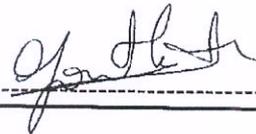
<u>Medical Device</u>	<u>UMDNS Code</u>	<u>Classification</u>
Algerbrush & Burr	15-621	Class I
Blade Breaker	15-621	Class I
Blade Holder	15-621	Class I
Calipers	15-621	Class I
Cannulas	15-621	Class I
Capsulorrhexis Forceps	15-621	Class I
Centering Device	15-621	Class I
Choppers	15-621	Class I
Cornea Trans Trephine Blades	15-621	Class I
Curettes	15-621	Class I
Depressors & Polishers	15-621	Class I
Diamond Knives	15-621	Class I
Dilators	15-621	Class I
Fixation Rings	15-621	Class I
Forceps	15-621	Class I
Gauges	15-621	Class I
Glaucoma Planer	15-621	Class I
Glaucoma Shaver	15-621	Class I
Hooks	15-621	Class I
I/A Handpiece & Bimanuals I/A	15-621	Class I
IOL Cutters	15-621	Class I
Irrigating Choppers & DuoMax	15-621	Class I
Knives	15-621	Class I
LASEK	15-621	Class I
Loops	15-621	Class I
Manipulators	15-621	Class I
Markers	15-621	Class I
Needle Holders	15-621	Class I
Prechoppers	15-621	Class I

Probe	15-621	Class I
Protectors	15-621	Class I
Pupil Expander	15-621	Class I
Retina	15-621	Class I
Retractors	15-621	Class I
Scissors	15-621	Class I
Spatulas	15-621	Class I
Specula	15-621	Class I
Spoons	15-621	Class I
Sterilization Trays	15-621	Class I
Sustainers	15-621	Class I
Titanium Instruments	15-621	Class I

Meet, (where applicable) the essential requirements of Council Directive 93/42/EEC pertaining to medical devices.

We hereby appoint mdi Europa GmbH, Wittekamp 30, D-30163 Hanover, Germany to act as European Authorized Representative as defined in Article 1, 2(g) of Directive 93/42/EEC

Signed this day 14 of July 2009



The necessary pre-requisites for placing the CE mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day of 14th of July 2009

mdi Europa
Wittekamp 30 · D-30163 Hanover
 Phone +49-511-39 08 93 30
 Fax +49-511-39 08 93 31

mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

Declaration of Conformity Certificate

We

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-1001	Class I
15-621	AE-1002	Class I
15-621	AE-1003	Class I
15-621	AE-1004	Class I
15-621	AE-1005	Class I
15-621	AE-1006	Class I
15-621	AE-1007	Class I
15-621	AE-1009	Class I
15-621	AE-1010	Class I
15-621	AE-1011	Class I
15-621	AE-1012	Class I
15-621	AE-1013	Class I
15-621	AE-1014	Class I
15-621	AE-1014A	Class I
15-621	AE-1014AN	Class I
15-621	AE-1014N	Class I
15-621	AE-1015	Class I
15-621	AE-1016	Class I
15-621	AE-1017	Class I
15-621	AE-1018	Class I
15-621	AE-1019	Class I
15-621	AE-1020	Class I
15-621	AE-1021	Class I
15-621	AE-1022	Class I
15-621	AE-1023	Class I
15-621	AE-1024	Class I
15-621	AE-1025	Class I
15-621	AE-1026	Class I
15-621	AE-1027	Class I
15-621	AE-1028	Class I
15-621	AE-1030	Class I
15-621	AE-1031	Class I
15-621	AE-1032	Class I

15-621	AE-1033	Class I
15-621	AE-1034	Class I
15-621	AE-1035	Class I
15-621	AE-1036	Class I
15-621	AE-1037	Class I
15-621	AE-1038N	Class I
15-621	AE-1039N	Class I
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15-621	AE-1040V	Class I
15-621	AE-1041N	Class I
15-621	AE-1041A	Class I
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15-621	AE-1041AS	Class I
15-621	AE-1041H	Class I
15-621	AE-1042N	Class I
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15-621	AE-1043A	Class I
15-621	AE-1043AN	Class I
15-621	AE-1043H	Class I
15-621	AE-1044N	Class I
15-621	AE-1044A	Class I
15-621	AE-1044H	Class I
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15-621	AE-1045H	Class I
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15-621	AE-1046A	Class I
15-621	AE-1046AN	Class I
15-621	AE-1046N	Class I
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15-621	AE-1082	Class I
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15-621	AE-1317	Class I
15-621	AE-1318	Class I
15-621	AE-1319	Class I
15-621	AE-1320	Class I
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15-621	AE-1340	Class I
15-621	AE-1400	Class I

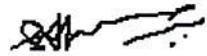
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15-621	AE-1504	Class I
15-621	AE-1505	Class I
15-621	AE-1510	Class I
15-621	AE-1511	Class I
15-621	AE-1512	Class I
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15-621	AE-1574T	Class I
15-621	AE-1575	Class I
15-621	AE-1576	Class I
15-621	AE-1577T	Class I
15-621	AE-1578	Class I
15-621	AE-1579	Class I
15-621	AE-1581T	Class I
15-621	AE-1582T	Class I
15-621	AE-1586	Class I
15-621	AE-1588	Class I
15-621	AE-1589	Class I
15-621	AE-1590	Class I
15-621	AE-1590T	Class I
15-621	AE-1591	Class I
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15-621	AE-1594	Class I
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15-621	AE-1650	Class I
15-621	AE-1651	Class I
15-621	AE-1660	Class I
15-621	AE-1661	Class I
15-621	AE-1662	Class I
15-621	AE-1670	Class I
15-621	AE-1675	Class I
15-621	AE-1676	Class I
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15-621	AE-1702	Class I
15-621	AE-1705	Class I
15-621	AE-1706	Class I
15-621	AE-1707	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V
 Classification per Annex IX: Class I
 Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . . of . DECEMBER . 2014 . . . 

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 3 of December 20 14

mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT



mdi Europa GmbH
 Langenhagener Str. 71, 30855 Langenhagen
 Phone +49-511-39 08 95 30
 Fax +49-511-39 08 98 39

Declaration of Conformity Certificate

We

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-2000	Class I
15-621	AE-2001	Class I
15-621	AE-2002	Class I
15-621	AE-2003	Class I
15-621	AE-2004	Class I
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15-621	AE-2523	Class I
15-621	AE-2524	Class I
15-621	AE-2525	Class I
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15-621	AE-2527	Class I
15-621	AE-2527L	Class I
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15-621	AE-2529	Class I
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15-621	AE-2531	Class I
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15-621	AE-2542	Class I
15-621	AE-2543	Class I
15-621	AE-2544	Class I
15-621	AE-2545	Class I
15-621	AE-2546	Class I
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15-621	AE-2550	Class I
15-621	AE-2551	Class I
15-621	AE-2552	Class I
15-621	AE-2553	Class I
15-621	AE-2554	Class I
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15-621	AE-2560	Class I
15-621	AE-2561	Class I
15-621	AE-2563	Class I
15-621	AE-2565	Class I

15-621	AE-2567	Class I
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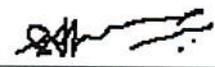
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15-621	AE-2935	Class I
15-621	AE-2939	Class I
15-621	AE-2950	Class I
15-621	AE-2951	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V
Classification per Annex IX: Class I
Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . of . DECEMBER . 2014 . 

<u>mdi Europa use only!</u>	
The necessary pre-requisites for placing the	CE mark on the above mentioned products
and marketing them in all Member States of the European Union have	been fulfilled.
Signed this day . 3 . of . December . 20 14	<small>mdi Europa GmbH Langenhagener Straße 71, 30855 Langenhagen Phone +49-511. 39 08 95 30 Fax +49-511. 39 08 95 39</small>
	 mdiEuropa THE MEDICAL DEVICE SERVICE-MANAGEMENT

Declaration of Conformity Certificate

We

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

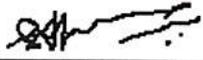
Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-3020	Class I
15-621	AE-3021	Class I
15-621	AE-3022	Class I
15-621	AE-3025	Class I
15-621	AE-3030	Class I
15-621	AE-3039	Class I
15-621	AE-3040	Class I
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15-621	AE-3254	Class I
15-621	AE-3255	Class I
15-621	AE-3260	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V
Classification per Annex IX: Class I
Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . of . DECEMBER . 2014 . 

mdi Europa use only!

The necessary pre-requisites for placing the  and marketing them in all Member States of the European Union have been fulfilled.

Signed this day 3 of December 2014


mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

mdi Europa GmbH
Langenhagener Str. 71 · 30855 Langenhagen
Phone +49-511-39 08 95 30
Fax +49-511-39 08 95 39

Declaration of Conformity Certificate

We

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-4000	Class I
15-621	AE-4001	Class I
15-621	AE-4002	Class I
15-621	AE-4010	Class I
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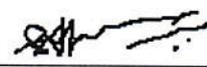
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15-621	AE-4826	Class I
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15-621	AE-4900N	Class I
15-621	AE-4901	Class I
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15-621	AE-4940	Class I
15-621	AE-4941	Class I
15-621	AE-4942	Class I
15-621	AE-4950	Class I
15-621	AE-4951	Class I

15-621	AE-4952	Class I
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15-621	AE-4961	Class I
15-621	AE-4962	Class I
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15-621	AE-4983	Class I
15-621	AE-4990	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V
 Classification per Annex IX: Class I
 Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . . of . DECEMBER . . 2014 

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 3 of December 2014


mdi Europa
 THE MEDICAL DEVICE SERVICE-MANAGEMENT

mdi Europa GmbH
 Langenhagener Str. 71 30855 Langenhagen
 Phone +49-511-39 08 95 39
 Fax +49-511-39 08 95 39

Declaration of Conformity Certificate

We

**ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA**

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-5000	Class I
15-621	AE-5001	Class I
15-621	AE-5002	Class I
15-621	AE-5003	Class I
15-621	AE-5010	Class I
15-621	AE-5011	Class I
15-621	AE-5012	Class I
15-621	AE-5013	Class I
15-621	AE-5014	Class I
15-621	AE-5015	Class I
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15-621	AE-5044	Class I
15-621	AE-5045N	Class I
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15-621	AE-5047	Class I
15-621	AE-5048	Class I
15-621	AE-5049	Class I
15-621	AE-5052N	Class I
15-621	AE-5054	Class I
15-621	AE-5056	Class I
15-621	AE-5060	Class I
15-621	AE-5062	Class I
15-621	AE-5100	Class I
15-621	AE-5101	Class I
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15-621	AE-5111	Class I
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15-621	AE-5220	Class I

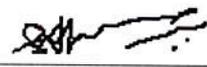
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15-621	AE-5740	Class I
15-621	AE-5741	Class I
15-621	AE-5762	Class I

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Conformity Assessment per Annex V
Classification per Annex IX: Class I
Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . of . DECEMBER . 2014 . 

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union have been fulfilled.

Signed this day 3 of December 2014


mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

mdi Europa GmbH
Langenhagener Str. 71 • 30855 Langenhagen
Phone +49-511-39 08 95 39
Fax +49-511-39 08 95 39

Declaration of Conformity Certificate

We

**ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA**

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-6000	Class I
15-621	AE-6000SNSC*	Class I
15-621	AE-6001	Class I
15-621	AE-6001SNSC*	Class I
15-621	AE-6010	Class I
15-621	AE-6010SNSC*	Class I
15-621	AE-6011	Class I
15-621	AE-6011SNSC*	Class I
15-621	AE-6100	Class I
15-621	AE-6100SNSC*	Class I
15-621	AE-6101	Class I
15-621	AE-6101SNSC*	Class I
15-621	AE-6101T	Class I
15-621	AE-6110	Class I
15-621	AE-6110SNSC*	Class I
15-621	AE-6111	Class I
15-621	AE-6111SNSC*	Class I
15-621	AE-6111T	Class I
15-621	AE-6130N	Class I
15-621	AE-6130SNSC*	Class I
15-621	AE-6131	Class I
15-621	AE-6131SNSC*	Class I
15-621	AE-6131T	Class I
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15-621	AE-6143	Class I
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15-621	AE-6151	Class I

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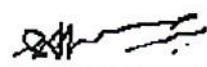
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Conformity Assessment per Annex V

Classification per Annex IX: Class I

Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . of . DECEMBER . 2014 . 

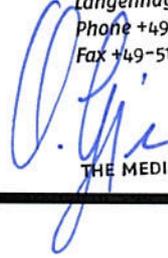
mdi Europa use only!

The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day . 3 . of . December . 2014

mdi Europa GmbH
Langenhagener Straße 71, 30855 Langenhagen
Phone +49-511. 39 08 95 30
Fax +49-511. 39 08 95 39



 mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

Declaration of Conformity Certificate

We

**ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA**

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-7000	Class I
15-621	AE-7001	Class I
15-621	AE-7002	Class I
15-621	AE-7003	Class I
15-621	AE-7004	Class I
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15-621	AE-7294	Class I
15-621	AE-7295	Class I

15-621	AE-7296	Class I
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15-621	AE-7304	Class I
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15-621	AE-7824	Class I
15-621	AE-7851	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V

Classification per Annex IX: Class I

Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . . of . DECEMBER . . 2014 . . . 

mdi Europa use only!

The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 3 of December 20 14

mdi Europa GmbH
Langenhagener Str. 71 · 30855 Langenhagen
Phone +49 511 39 08 95 30
Fax +49 511 39 08 95 39


mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

15-621	AE7-3060S	Class I
15-621	AE7-3061	Class I
15-621	AE7-3061S	Class I
15-621	AE7-3062	Class I
15-621	AE7-3062S	Class I

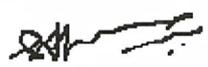
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Conformity Assessment per Annex V

Classification per Annex IX: Class I

Notified Body: 0086 BSI, UK

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Signed this day . 2 . of . FEBRUARY . 2016 . 

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have been fulfilled.

Signed this day . 2 . of . February . 2016 .


mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

and on the above mentioned products and marketing them in all Member States of the European Union, have been fulfilled.
 Phone +49-511. 39 08 95 30
 Fax +49-511. 39 08 95 39

Declaration of Conformity Certificate

We

**ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA**

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	AE-8000	Class I
15-621	AE-8001	Class I
15-621	AE-8002	Class I
15-621	AE-8003	Class I
15-621	AE-8005	Class I
15-621	AE-8090	Class I
15-621	AE-8100	Class I
15-621	AE-8101	Class I
15-621	AE-8102	Class I
15-621	AE-8103	Class I
15-621	AE-8104	Class I
15-621	AE-8105	Class I
15-621	AE-8106	Class I
15-621	AE-8107	Class I
15-621	AE-8108	Class I
15-621	AE-8109	Class I
15-621	AE-8110	Class I
15-621	AE-8111	Class I
15-621	AE-8112	Class I
15-621	AE-8114	Class I
15-621	AE-8115	Class I
15-621	AE-8116	Class I
15-621	AE-8117	Class I
15-621	AE-8118	Class I
15-621	AE-8119	Class I
15-621	AE-8120	Class I
15-621	AE-8121	Class I
15-621	AE-8122	Class I
15-621	AE-8122A	Class I
15-621	AE-8124	Class I
15-621	AE-8125	Class I
15-621	AE-8126	Class I
15-621	AE-8127	Class I

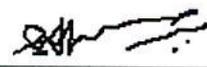
15-621	AE-8128	Class I
15-621	AE-8129	Class I
15-621	AE-8130	Class I
15-621	AE-8131	Class I
15-621	AE-8132	Class I
15-621	AE-8133	Class I
15-621	AE-8134	Class I
15-621	AE-8135	Class I
15-621	AE-8135M	Class I
15-621	AE-8136	Class I
15-621	AE-8137	Class I
15-621	AE-8138	Class I
15-621	AE-8139	Class I
15-621	AE-8140	Class I
15-621	AE-8141	Class I
15-621	AE-8142	Class I
15-621	AE-8143	Class I
15-621	AE-8144	Class I
15-621	AE-8145	Class I
15-621	AE-8146	Class I
15-621	AE-8147	Class I
15-621	AE-8147S	Class I
15-621	AE-8148	Class I
15-621	AE-8149	Class I
15-621	AE-8150	Class I
15-621	AE-8151	Class I
15-621	AE-8153	Class I
15-621	AE-8155	Class I
15-621	AE-8156	Class I
15-621	AE-8157	Class I
15-621	AE-8158	Class I
15-621	AE-8159	Class I
15-621	AE-8160	Class I
15-621	AE-8161	Class I
15-621	AE-8162	Class I
15-621	AE-8163	Class I
15-621	AE-8164	Class I
15-621	AE-8165	Class I
15-621	AE-8167	Class I
15-621	AE-8168	Class I
15-621	AE-8169	Class I
15-621	AE-8170	Class I
15-621	AE-8171	Class I
15-621	AE-8172	Class I
15-621	AE-8173	Class I
15-621	AE-8175	Class I
15-621	AE-8176	Class I
15-621	AE-8177	Class I

15-621	AE-8178	Class I
15-621	AE-8179	Class I
15-621	AE-8180	Class I
15-621	AE-8181	Class I
15-621	AE-8184	Class I
15-621	AE-8185	Class I
15-621	AE-8186	Class I
15-621	AE-8187	Class I
15-621	AE-8188	Class I
15-621	AE-8189	Class I
15-621	AE-8190	Class I
15-621	AE-8191	Class I
15-621	AE-8192	Class I
15-621	AE-8193	Class I
15-621	AE-8194	Class I
15-621	AE-8194A	Class I
15-621	AE-8195	Class I
15-621	AE-8196	Class I
15-621	AE-8197	Class I
15-621	AE-8198	Class I
15-621	AE-8199	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V
 Classification per Annex IX: Class I
 Notified Body: 0086 BSI, UK

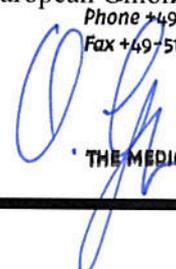
We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 2 . of . DECEMBER . 2014 

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The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day 3 of December 20 14



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THE MEDICAL DEVICE SERVICE-MANAGEMENT

Langenhagener Str. 71 30855 Langenhagen
 Phone +49-511. 39 08 95 30
 Fax +49-511. 39 08 95 39

Declaration of Conformity Certificate

We **ASICO LLC**
26 Plaza Drive
Westmont
IL 60559
USA

Declare with sole responsibility, that our product/s:

<u>Medical Device</u>	<u>UMDNS Code</u>	<u>Classification</u>
AE-9063CSP	17-543	Class I

Meet, (where applicable) the essential requirements of Council Directive 93/42/EEC pertaining to medical devices.

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71 30855 Hannover-Langenhagen, Germany to act as European Authorized Representative as defined in Article 1, 2(g) of Directive 93/42/EEC

Signed this day 29 of November, 2011

[Signature]

The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day of 29th of November 2011

mdi Europa GmbH
Langenhagener Str. 71 30855 Hannover
Tel +49 511 39 08 95 39
Fax +49 511 39 08 95 39

[Signature] **mdi Europa**
THE MEDICAL DEVICE SERVICE-MANAGEMENT

Declaration of Conformity Certificate

We **ASICO LLC** .
26 Plaza Drive
Westmont, IL 60559
U.S.A

Declare with sole responsibility, that our product/s:

<u>UMDNS CODE</u>	<u>Product description</u>	<u>Classification</u>
17-543	Inserters	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC OR Council Directive 98/79/EEC pertaining to medical devices.

We hereby appoint mdi Europa GmbH, Wittekamp 30, D - 30163 Hanover, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day 20 of November. 2007

[Handwritten Signature]

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The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day *21* of *Nov* 20 *07*

[Handwritten Signature]

Wittekamp 30 · D-30163 Hanover
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 Fax +49-511. 39 08 95 39


mdiEuropa
THE MEDICAL DEVICE SERVICE MANAGEMENT

Declaration of Conformity Certificate

We

ASICO LLC
26 Plaza Drive
Westmont
IL 60559, USA

Declare with sole responsibility, that our product/s:

UMDNS Code	Code Description	Classification
15-621	SP-121832	Class I
15-621	AE-2558	Class I

meet, the essential requirements of EITHER Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to medical devices.

Conformity Assessment per Annex V

Classification per Annex IX: Class I

Notified Body: 0086 BSI, UK

We hereby appoint mdi Europa GmbH, Langenhagener Straße 71, D - 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day . 4 . . of . JANUARY . . 2017 

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 4 . . of January 2017

mdi Europa GmbH
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mdi Europa

THE MEDICAL DEVICE SERVICE MANAGEMENT