

EC Certificate - Full Quality Assurance System

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

No. CE 630687
Issued To: **Incipio Devices**
82 Commercial Rd.
Huntington
Indiana
46750
USA

In respect of:

Design and manufacture of acetabular reamers and reamer handles for end-user sterilization

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-09-28**

Date: **2020-04-21**

Expiry Date: **2024-05-26**

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Incipio Devices SA Av. des Pâquiers 16 St-Blaise 2072 Switzerland	EU Representative Manufacture
Lastec AG Mattenstrasse 6 Brügg 2555 Switzerland	Crucial Supplier
MTG Mécanique de Précision Sàrl La Chaux 14 Lamboing 2516 Switzerland	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
28 September 2015	8283320	First Issue.
20 February 2019	8424645	Traceable to NB 0086. Administrative change to subcontractor 'Lauener & Cie SA' from 'Inspection' to 'Final Inspection'.
22 August 2019	3039820	Update EU Representative Address. Removal of significant subcontractors 'Lauener & Cie. SA' and 'Niklaus SA'.
Current	3045228	Certificate Renewal

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