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EC Design-Examination Certificate

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

No. **CE 631876**

Issued To: **DePuy International Limited**
Trading as DePuy CMW
Cornford Road
Blackpool
Lancashire
FY4 4QQ
United Kingdom

In respect of:

Cranioplastic®

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **24 July 2015** Date: **20 January 2016** Expiry Date: **23 July 2020**

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Supplementary Information to CE 631876

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Product Code	Description
431280	Cranioplastic®

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Certificate History

Date	Reference Number	Action
24 July 2015	10154068	First Issue
20 January 2016	10158836	Approval of packaging change due to new Tyvek® 1073B packaging material, impacting all product codes.

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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