

**I, PETER A BEECH**, of the Town of Slough,  
Berkshire, Notary Public duly admitted and sworn,  
practising in the said Town,

**DO HEREBY CERTIFY AND ATTEST:**

**THAT** the original document hereunto annexed  
namely Statement dated 8th April 2008 and signed for  
on behalf of DePuy International Ltd by Linda Porter,  
Senior Regulatory Affairs Associate is genuine and authentic.

**TESTIMONY WHEREOF** I have hereunto set my  
hand and affixed my Seal of Office, in the Town of  
Slough aforesaid, this Wednesday, 9th April 2008.

CE 514067  
CHARW 657



**MR PETER A BEECH**

*Notary Public  
Charsley Harrison Solicitors  
4 Burlington Court  
Burlington Road  
Slough, SL1 2JS*

ATTESTED BY  
**PETER A. BEECH**  
Notary Public  
4 BURLINGTON COURT,  
SLOUGH, SL1 2JS ENGLAND



8 April 2008

**DePuy International Ltd**

Number One  
White Rose Office Park  
Millshaw Park Lane  
Leeds LS11 0EA  
England

Tel: +44 (0)113 387 7800

Fax: +44 (0)113 387 7890

**STATEMENT**

As a responsible representative of DePuy International Limited, I hereby certify that the following documents are complete and accurate copies of the originals.

**Design Examination Certificates**

No. CE 514067 Charnley Hip System

No. CE 510433 C-Stem Hip Prosthesis

No. CE 524612 Duraloc Acetabular Cup System

.....*L. E. Porter*.....

**Linda Porter**

**Senior Regulatory Affairs Associate**

# Certificate



## Design Examination

No. CE 510433

Issued to:

**DePuy International Limited**  
**St Anthony's Road**  
**Leeds**  
**LS11 8DT**  
**United Kingdom**

In respect of:

**C Stem Hip Prosthesis**

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4 and Commission Directive 2005/50/EC.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Alastair Trivett, Managing Director, BSI Product Services – Global

First issued: 24 Sep 2007

Date: 21 Dec 2007

Expiration Date: 13 Dec 2011

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### Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.



**BSI Product Services**

Kitemark House, Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ United Kingdom

Tel: +44 (0)450 755000 [www.bsi.com](http://www.bsi.com)

# Certificate

## Supplementary Information to CE 510433

Issued to:  
DePuy International Limited

Leeds  
United Kingdom

Product: C Stem Hip Prosthesis

| Product Code | Description               |
|--------------|---------------------------|
| 961100000    | Asian C-Stem Implant sz0A |
| 961100500    | Asian C-Stem Implant sz1A |
| 961101500    | Asian C-Stem Implant sz2A |
| 961102500    | Asian C-Stem Implant sz3A |
| 961315000    | C-Stem High Offset sz2    |
| 961160000    | C-Stem CDH                |
| 961170000    | C-Stem High Offset sz3    |
| 961172000    | C-Stem High Offset sz4    |
| 961174000    | C-Stem High Offset sz5    |
| 961161000    | C-Stem Primary sz1        |
| 961162000    | C-Stem Primary sz2        |
| 961163000    | C-Stem Primary sz3        |
| 961164000    | C-Stem Primary sz4        |
| 961165000    | C-Stem Primary sz5        |
| 961166000    | C-Stem Primary sz6        |
| 961167000    | C-Stem Primary sz7        |
| 961168000    | C-Stem Primary sz8        |

| Product Code | Description                |
|--------------|----------------------------|
| 157004070    | C Stem AMT Sz 1 std Offset |
| 157004085    | C Stem AMT Sz 2 std Offset |
| 157004090    | C Stem AMT Sz 3 std Offset |
| 157004100    | C Stem AMT Sz 4 std Offset |
| 157004110    | C Stem AMT Sz 5 std Offset |
| 157004120    | C Stem AMT Sz 6 std Offset |
| 157004135    | C Stem AMT Sz 7 std Offset |
| 157004150    | C Stem AMT Sz 8 std Offset |

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BSI Product Services

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# Certificate

## Supplementary Information to CE 510433

Issued to:  
DePuy International Limited

Leeds  
United Kingdom

| Product Code | Description                    |
|--------------|--------------------------------|
| 157014070    | C Stem AMT Sz 1 HI Offset      |
| 157014085    | C Stem AMT Sz 2 HI Offset      |
| 157014090    | C Stem AMT Sz 3 HI Offset      |
| 157014100    | C Stem AMT Sz 4 HI Offset      |
| 157014110    | C Stem AMT Sz 5 HI Offset      |
| 157014120    | C Stem AMT Sz 6 HI Offset      |
| 157014135    | C Stem AMT Sz 7 HI Offset      |
| 157014150    | C Stem AMT Sz 8 HI Offset      |
| 157024060    | C Stem AMT RSA Sz 2 Std Offset |
| 157024000    | C Stem AMT RSA Sz 2 HI Offset  |
| 157024070    | C Stem AMT RSA Sz 3 Std Offset |
| 157024080    | C Stem AMT RSA Sz 4 Std Offset |
| 157024090    | C Stem AMT RSA Sz 5 Std Offset |
| 157024100    | C Stem AMT RSA Sz 3 HI Offset  |
| 157024110    | C Stem AMT RSA Sz 4 HI Offset  |
| 157024120    | C Stem AMT RSA Sz 5 HI Offset  |
| 961161001    | C Stem Sz 1 RSA                |
| 961162001    | C Stem Sz 2 RSA                |
| 961163001    | C Stem Sz 3 RSA                |
| 961164001    | C Stem Sz 4 RSA                |
| 961307000    | C Stem Revision Sz 4 x 200mm   |
| 961308000    | C Stem Revision Sz 4 x 240mm   |
| 961309000    | C Stem Revision Sz 6 x 200mm   |
| 961310000    | C Stem Revision Sz 6 x 240mm   |
| 961311000    | C Stem Revision Sz 8 x 200mm   |
| 961312000    | C Stem Revision Sz 8 x 240mm   |
| 998500000    | C Stem Sz 2 Long               |
| 998500001    | C Stem Sz 4 Long               |
| 998500002    | C Stem Sz 6 Long               |

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# Certificate

## Supplementary Information to CE 510433

Issued to:  
DePuy International Limited

Leeds  
United Kingdom

### History to Certificate

| Date:             | Reference No.: | Action:  |
|-------------------|----------------|--|
| 24 September 2007 | 10080991       | First issue in line with 2005/50/EC  |
| 21 December 2007  | 10091913       | Addition of C Stem AMT, C Stem AMT RSA, C Stem Revision and C Stem Long products |

First Issued: 24 Sep 2007  
Expiration Date: 13 Dec 2011

Date: 21 Dec 2007

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# Certifikát

## Preskúmanie dizajnu

Č. CE 510433

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Vydaný spoločnosti:

**DePuy International Limited**  
**St Anthony's Road**  
**Leeds**  
**LS11 8DT**  
**Spojené kráľovstvo**

Vo veci:

**Bedrová endoprotéza C-Stem.**

Na základe preskúmania podľa požiadaviek smernice Rady 93/42/EHS, príloha II, odsek 4 a smernice Komisie 2005/50/ES.

Za a v mene Ústavu pre britské normy (British Standards Institutions), ktorý je notifikovaným orgánom pre účely vyššie uvedenej smernice (číslo notifikovaného orgánu 0086):

*Nečitateľný podpis*

Alastair Trivett, výkonný riaditeľ, BSI Product Services – Global

Dátum prvého vydania: **24. september 2007**

Dátum: **21. december 2007**

Dátum platnosti: **13. december 2011**

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### Podmienky schválenia

Platnosť tohto certifikátu je podmienená udržiavaním systému kvality podľa požiadaviek predmetnej smernice.

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**BSI Product Services**

Kitemark House, Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ, Spojené kráľovstvo  
Tel.: +44 (0)8450 765600, www.bsigroup.com

# Certifikát

## Doplňujúce informácie k certifikátu CE 510433

Vydaný spoločnosťou:  
**DePuy International Limited**

**Leeds**  
**Spojené kráľovstvo**

**Produkt:** Bedrová endoprotéza C-Stem

| Kód produktu | Popis |
|--------------|-------|
|--------------|-------|

| Kód produktu | Popis |
|--------------|-------|
|--------------|-------|

Dátum prvého vydania: **24. september 2007**  
Dátum platnosti: **13. december 2011**

Dátum: **21. december 2007**

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Tel.: +44 (0)8450 765600, [www.bsigroup.com](http://www.bsigroup.com)



# Certifikát

## Doplňujúce informácie k certifikátu CE 510433

Vydaný spoločnosti:  
**DePuy International Limited**

**Leeds**  
**Spojené kráľovstvo**

### Prehľad zmien v certifikáte

| Dátum              | Referenčné číslo | Úkon  |
|--------------------|------------------|---|
| 24. september 2007 | 10080991         | Prvé vydanie v súlade so smernicou 2005/50/ES.                                |
| 21. december 2007  | 10091913         | Pridanie produktov C Stem AMT, C Stem AMT RSA, C Stem Revision a C Stem Long. |

Dátum prvého vydania: **24. september 2007**  
Dátum platnosti: **13. december 2011**

Dátum: **21. december 2007**

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**Prekladateľská doložka:**

Preklad som vypracoval ako prekladateľ zapísaný v zozname znalcov, tlmočníkov a prekladateľov, ktorý vedie Ministerstvo spravodlivosti Slovenskej republiky v odbore jazyk slovenský – anglický, evidenčné číslo prekladateľa: 970889. Prekladateľský úkon je zapísaný pod poradovým číslom <sup>137</sup> prekladateľského denníka č. 1. Za prekladateľský úkon a vzniknuté náklady účtujem podľa vyúčtovania na základe priloženého dokladu č. 237/10.

Mgr. Rastislav Majorský

30.3. 2010



