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# EC Certificate - Full Quality Assurance System

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

**No.** **CE 01821**

Issued To: **Sanatmetal Orthopaedic & Traumatologic Equipment Manufacturer Ltd**
**Eger**
**Faiskola u.5**
**H-3300**
**Hungary**

In respect of:

**For the design, development and manufacture of sterile and non-sterile trauma implants, dental screws and spinal implants, and associated instruments.**

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):

Gary Fenton, Global Assurance Director

First Issued: **10 December 1997** Date: **10 September 2014** Expiry Date: **12 September 2019**

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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 01821** |
| Date: | **10 September 2014** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Dispomedicor Zrt.<br>Furedi ut 98<br>H-4032, Debrecen<br>Hungary | **Gamma Sterilization** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01821**

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**H-3300**
**Hungary**

| Date | Reference Number | Action |
|---|---|---|
| 10 December 1997 | - | First Issue |
| 13 September 1999 | - | Change of Company name from "DePuy Sanatmetal" to "Sanatmetal Orthopaedic and Traumatalogic Equipment Manufacturer Ltd" |
| 01 August 2003 | - | 5 Year review and change of scope to include sterile hip prostheses and the addition of "Dispomedicor RT" (Hungary as a subcontractor |
| 28 September 2009 | 7296984 | Certificate renewal, modification to certificate scope removal of "design, development and manufacture of sterile hip prostheses sterile hip prostheses" and correction to company name from "Traumatalogic" to "Traumatologic". Further modification to certificate scope to, "For the design, development and manufacture of sterile and non-sterile trauma implants, dental screws and thoraco-lumbar transpedicular spinal implants, and associated instruments." Change of subcontractor activity from "sterilization" to "Gamma Sterilization" and Subcontractor name change, from "Dispomedicor Rt" to "Dispomedicor Zrt." |
| 10 September 2014 | 8224249 | Certificate Renewal<br>Change to scope from "thoraco-lumbar transpedicular spinal implants" to "spinal implants" |