By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 98427**

Issued To: **Kobayashi Healthcare Europe Limited**
Power Road Studios
114 Power Road
London
W4 5PY
United Kingdom

In respect of:

The manufacture and final inspection of heat packs/patches for hot therapy.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2005-08-19** Date: **2021-03-09** Expiry Date: **2024-05-26**

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Supplementary Information to CE 98427

Issued To:

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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD1402	Heat Patch	NA for class IIa devices

First Issued: **2005-08-19** Date: **2021-03-09** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 98427**
Date:	**2021-03-09**
Issued To:	**Kobayashi Healthcare Europe Limited** **Power Road Studios** **114 Power Road** **London** **W4 5PY** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Medical Device Management Ltd Block B, The Crescent Building Northwood Santry Dublin 9 D09 C6X8 Ireland	**EU Representative**
Medical Device Management Ltd 31 Braintree Business Park Blackwell Drive Braintree Essex CM7 2PU United Kingdom	**Final Inspection** **Testing**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 98427**
Date: **2021-03-09**
Issued To: **Kobayashi Healthcare Europe Limited**
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Date	Reference Number	Action
19 August 2005		First issue
10 May 2006		Change of address to '272 Gunnersbury Avenue, Chiswick'
11 December 2009	7460644	Certificate re-issue due to change of scope from 'The final inspection and test of heat pads' to 'The final inspection and test of heat packs/patches and cooling packs for hot and cold therapy'
17 August 2010	7475413	Certificate renewal
22 July 2015	8292877	Certificate renewal, change of subcontractor address for Medical Device Management Ltd to 31 Braintree Business Park, Blackwell Drive, Braintree, Essex, CM7 2PU
6 March 2019	7780224	Traceable to NB 0086.
22 October 2019	3040756	Change of address to 'Power Road Studios, 114 Power Road, London'. Addition of product table.
16 July 2020	3261263	Renewal. Removed Ice packs for cooling therapy from scope.
Current	3387324	Changed certificate from Annex VI to Annex V and added 'Manufacture' to scope. Addition of new EC Representative 'Medical Device Management Ltd'.