

EC Design-Examination Certificate

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

No.**CE 535012****Issued To:**

**Smith & Nephew, Inc.
1450 Brooks Rd.
Memphis
Tennessee
38116
USA**

In respect of:

Legion Crosslinked Polyethylene (XLPE) Articular inserts

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-03-13**

Date: **2020-07-03**

Expiry Date: **2024-03-12**

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Supplementary Information to CE 535012

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
71453101	LEGION CR HIGH FLEX XLPE	1-2 9MM	Total Knee Replacement	III
71453181	LEGION CR HIGH FLEX XLPE	1-2 10MM	Total Knee Replacement	III
71453102	LEGION CR HIGH FLEX XLPE	1-2 11MM	Total Knee Replacement	III
71453182	LEGION CR HIGH FLEX XLPE	1-2 12MM	Total Knee Replacement	III
71453103	LEGION CR HIGH FLEX XLPE	1-2 13MM	Total Knee Replacement	III
71453104	LEGION CR HIGH FLEX XLPE	1-2 15MM	Total Knee Replacement	III
71453105	LEGION CR HIGH FLEX XLPE	1-2 18MM	Total Knee Replacement	III
71453111	LEGION CR HIGH FLEX XLPE	3-4 9MM	Total Knee Replacement	III
71453183	LEGION CR HIGH FLEX XLPE	3-4 10MM	Total Knee Replacement	III
71453112	LEGION CR HIGH FLEX XLPE	3-4 11MM	Total Knee Replacement	III

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71453184	LEGION CR HIGH FLEX XLPE	3-4 12MM	Total Knee Replacement	III
71453113	LEGION CR HIGH FLEX XLPE	3-4 13MM	Total Knee Replacement	III
71453114	LEGION CR HIGH FLEX XLPE	3-4 15MM	Total Knee Replacement	III
71453115	LEGION CR HIGH FLEX XLPE	3-4 18MM	Total Knee Replacement	III
71453121	LEGION CR HIGH FLEX XLPE	5-6 9MM	Total Knee Replacement	III
71453185	LEGION CR HIGH FLEX XLPE	5-6 10MM	Total Knee Replacement	III
71453122	LEGION CR HIGH FLEX XLPE	5-6 11MM	Total Knee Replacement	III
71453186	LEGION CR HIGH FLEX XLPE	5-6 12MM	Total Knee Replacement	III
71453123	LEGION CR HIGH FLEX XLPE	5-6 13MM	Total Knee Replacement	III

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71453124	LEGION CR HIGH FLEX XLPE	5-6 15MM	Total Knee Replacement	III
71453125	LEGION CR HIGH FLEX XLPE	5-6 18MM	Total Knee Replacement	III
71453131	LEGION CR HIGH FLEX XLPE	7-8 9MM	Total Knee Replacement	III
71453187	LEGION CR HIGH FLEX XLPE	7-8 10MM	Total Knee Replacement	III
71453132	LEGION CR HIGH FLEX XLPE	7-8 11MM	Total Knee Replacement	III
71453188	LEGION CR HIGH FLEX XLPE	7-8 12MM	Total Knee Replacement	III
71453133	LEGION CR HIGH FLEX XLPE	7-8 13MM	Total Knee Replacement	III
71453134	LEGION CR HIGH FLEX XLPE	7-8 15MM	Total Knee Replacement	III
71453135	LEGION CR HIGH FLEX XLPE	7-8 18MM	Total Knee Replacement	III
71453201	LEGION PS HIGH FLEX XLPE	1-2 9MM	Total Knee Replacement	III

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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71453171	LEGION PS HIGH FLEX XLPE	1-2 10MM	Total Knee Replacement	III
71453202	LEGION PS HIGH FLEX XLPE	1-2 11MM	Total Knee Replacement	III
71453172	LEGION PS HIGH FLEX XLPE	1-2 12MM	Total Knee Replacement	III
71453203	LEGION PS HIGH FLEX XLPE	1-2 13MM	Total Knee Replacement	III
71453204	LEGION PS HIGH FLEX XLPE	1-2 15MM	Total Knee Replacement	III
71453205	LEGION PS HIGH FLEX XLPE	1-2 18MM	Total Knee Replacement	III
71453206	LEGION PS HIGH FLEX XLPE	1-2 21MM	Total Knee Replacement	III
71453207	LEGION PS HIGH FLEX XLPE	1-2 25MM	Total Knee Replacement	III
71453211	LEGION PS HIGH FLEX XLPE	3-4 9MM	Total Knee Replacement	III
71453173	LEGION PS HIGH FLEX XLPE	3-4 10MM	Total Knee Replacement	III

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71453212	LEGION PS HIGH FLEX XLPE	3-4 11MM	Total Knee Replacement	III
71453174	LEGION PS HIGH FLEX XLPE	3-4 12MM	Total Knee Replacement	III
71453213	LEGION PS HIGH FLEX XLPE	3-4 13MM	Total Knee Replacement	III
71453214	LEGION PS HIGH FLEX XLPE	3-4 15MM	Total Knee Replacement	III
71453215	LEGION PS HIGH FLEX XLPE	3-4 18MM	Total Knee Replacement	III
71453216	LEGION PS HIGH FLEX XLPE	3-4 21 MM	Total Knee Replacement	III
71453217	LEGION PS HIGH FLEX XLPE	3-4 25MM	Total Knee Replacement	III
71453221	LEGION PS HIGH FLEX XLPE	5-6 9MM	Total Knee Replacement	III
71453175	LEGION PS HIGH FLEX XLPE	5-6 10MM	Total Knee Replacement	III
71453222	LEGION PS HIGH FLEX XLPE	5-6 11MM	Total Knee Replacement	III

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71453176	LEGION PS HIGH FLEX XLPE	5-6 12MM	Total Knee Replacement	III
71453223	LEGION PS HIGH FLEX XLPE	5-6 13MM	Total Knee Replacement	III
71453224	LEGION PS HIGH FLEX XLPE	5-6 15MM	Total Knee Replacement	III
71453225	LEGION PS HIGH FLEX XLPE	5-6 18MM	Total Knee Replacement	III
71453226	LEGION PS HIGH FLEX XLPE	5-6 21MM	Total Knee Replacement	III
71453227	LEGION PS HIGH FLEX XLPE	5-6 25MM	Total Knee Replacement	III
71453231	LEGION PS HIGH FLEX XLPE	7-8 9MM	Total Knee Replacement	III
71453177	LEGION PS HIGH FLEX XLPE	7-8 10MM	Total Knee Replacement	III
71453232	LEGION PS HIGH FLEX XLPE	7-8 11MM	Total Knee Replacement	III
71453178	LEGION PS HIGH FLEX XLPE	7-8 12MM	Total Knee Replacement	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
71453233	LEGION PS HIGH FLEX XLPE	7-8 13MM	Total Knee Replacement	III
71453234	LEGION PS HIGH FLEX XLPE	7-8 15MM	Total Knee Replacement	III
71453235	LEGION PS HIGH FLEX XLPE	7-8 18MM	Total Knee Replacement	III
71453236	LEGION PS HIGH FLEX XLPE	7-8 21MM	Total Knee Replacement	III
71453237	LEGION PS HIGH FLEX XLPE	7-8 25MM	Total Knee Replacement	III
71453271	LEGION XLPE DISHED INSERT	1-2 9MM	Total Knee Replacement	III
71453272	LEGION XLPE DISHED INSERT	1-2 11MM	Total Knee Replacement	III
71453273	LEGION XLPE DISHED INSERT	1-2 13MM	Total Knee Replacement	III
71453274	LEGION XLPE DISHED INSERT	1-2 15MM	Total Knee Replacement	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
71453275	LEGION XLPE DISHED INSERT	1-2 18MM	Total Knee Replacement	III
71453276	LEGION XLPE DISHED INSERT	1-2 21MM	Total Knee Replacement	III
71453277	LEGION XLPE DISHED INSERT	3-4 9MM	Total Knee Replacement	III
71453278	LEGION XLPE DISHED INSERT	3-4 11MM	Total Knee Replacement	III
71453279	LEGION XLPE DISHED INSERT	3-4 13MM	Total Knee Replacement	III
71453281	LEGION XLPE DISHED INSERT	3-4 15MM	Total Knee Replacement	III
71453282	LEGION XLPE DISHED INSERT	3-4 18MM	Total Knee Replacement	III
71453283	LEGION XLPE DISHED INSERT	3-4 21 MM	Total Knee Replacement	III
71453284	LEGION XLPE DISHED INSERT	5-6 9MM	Total Knee Replacement	III
71453285	LEGION XLPE DISHED INSERT	5-6 11MM	Total Knee Replacement	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
71453286	LEGION XLPE DISHED INSERT	5-6 13MM	Total Knee Replacement	III
71453287	LEGION XLPE DISHED INSERT	5-6 15MM	Total Knee Replacement	III
71453288	LEGION XLPE DISHED INSERT	5-6 18MM	Total Knee Replacement	III
71453289	LEGION XLPE DISHED INSERT	5-6 21MM	Total Knee Replacement	III
71453291	LEGION XLPE DISHED INSERT	7-8 9MM	Total Knee Replacement	III
71453292	LEGION XLPE DISHED INSERT	7-8 11MM	Total Knee Replacement	III
71453293	LEGION XLPE DISHED INSERT	7-8 13MM	Total Knee Replacement	III
71453294	LEGION XLPE DISHED INSERT	7-8 15MM	Total Knee Replacement	III
71453295	LEGION XLPE DISHED INSERT	7-8 18MM	Total Knee Replacement	III
71453296	LEGION XLPE DISHED INSERT	7-8 21MM	Total Knee Replacement	III

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Certificate History

Date	Reference Number	Action
13 March 2009	10095796	First issue.
22 August 2012	10129962	Addition of multiple product codes for XLPE insert components.
11 March 2014	10144502	Certificate Renewal.
29 June 2015	10154433	Alterations to the way that product descriptions appear on this certificate, including a change from 'Deep Flex' to High Flex'. No changes to the devices.
08 July 2016	10162413	Reviewed for application of Tyvek transition packaging material.
12 September 2016	10154766	Addition of LEGION CR High Flex XLPE Inserts (10mm and 12mm), catalogue No. 71453181 to 71453188, and LEGION PS High Flex XLPE Inserts (10mm and 12mm), catalogue No. 71453171 to 71453178.
24 January 2019	9633192	Packaging lid adhesive change.
14 February 2019	8587602	Traceable to NB 0086.
12 March 2019	9641052	Certificate Renewal. Approval of IFU update to include warnings related to patella resurfacing. Removal of product codes for Legion XLPE CR Inserts (7143141 to 71453162) and Legion XLPE PS inserts (71453241 to 71453262).

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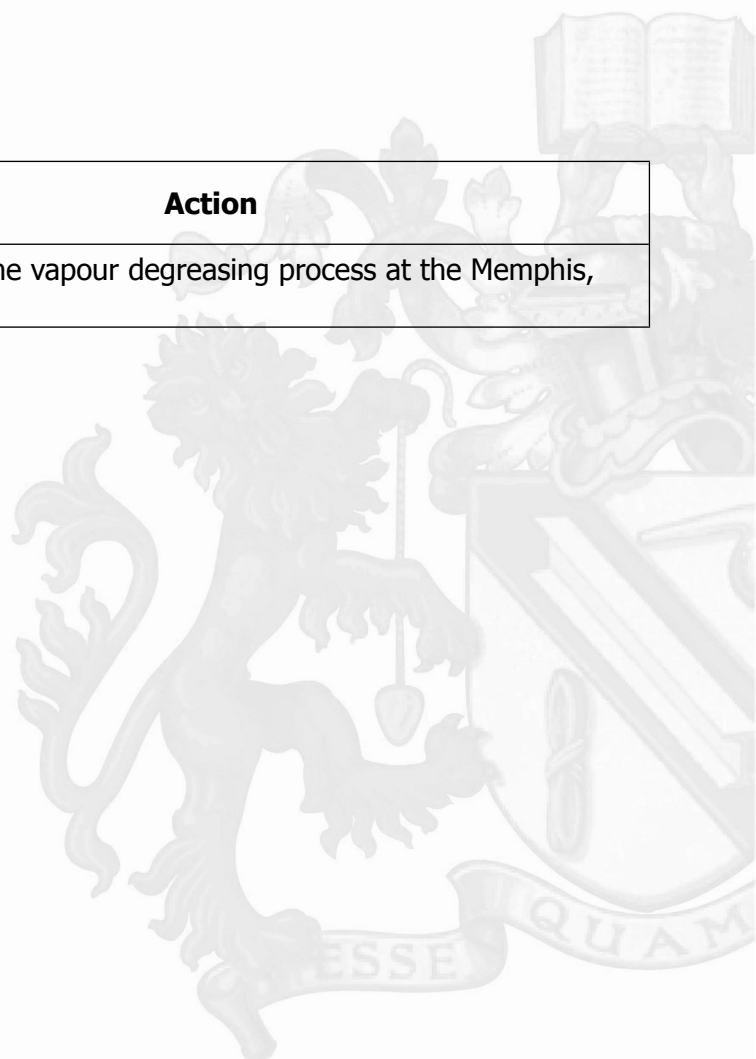
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Date	Reference Number	Action
Current	3041434	Automation of the vapour degreasing process at the Memphis, USA location

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