

EC Design-Examination Certificate

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

No.

CE 518880

Issued To:

**Smith & Nephew Medical Ltd
101 Hessle Road
Hull
North Humberside
HU3 2BN
United Kingdom**

In respect of:

ALLEVYN Ag Dressings

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: **27 September 2007**

Date: **19 May 2015**

Expiry Date: **26 September 2017**

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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.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 518880

Issued To:

Smith & Nephew Medical Ltd
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ALLEVYN Ag Adhesive:

Size
7.5cm x 7.5cm, Carton of 10
7.5cm x 7.5cm, Carton of 10
7cm x 8cm, Carton of 3 (German variant - ALLEVYN Silber Schaumverband Haftend)
7cm x 8cm, Carton of 12 (German variant - ALLEVYN Silber Schaumverband Haftend)
7cm x 8cm, Carton of 20 (German variant - ALLEVYN Silber Schaumverband Haftend)
10cm x 10cm, Carton of 10
10cm x 10cm, Carton of 10
9.5cm x 11cm, Carton of 12 (German variant - ALLEVYN Silber Schaumverband Haftend)
9.5cm x 11cm, Carton of 20 (German variant - ALLEVYN Silber Schaumverband Haftend)
12cm x 13cm, Carton of 12 (German variant - ALLEVYN Silber Schaumverband Haftend)
12cm x 13cm, Carton of 20 (German variant - ALLEVYN Silber Schaumverband Haftend)
12.5cm x 12.5cm, Carton of 10
12.5cm x 12.5cm, Carton of 3 (Spanish variant – ALLEVYN Plata Adhesive)
12.5cm x 12.5cm, Carton of 10
12.5cm x 12.5cm, Carton of 16 (French variant – ALLEVYN S.Ag Adhesive)
15cm x 15cm, Carton of 3 (Spanish variant – ALLEVYN Plata Adhesive)

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ALLEVYN Ag Adhesive (continued):

Size
17.5cm x 17.5cm, Carton of 10
17.5cm x 17.5cm, Carton of 10
17.5cm x 17.5cm, Carton of 10 (French variant – ALLEVYN S.Ag Adhesive)
17cm x 18cm, Carton of 12 (German variant - ALLEVYN Silber Schaumverband Haftend)
17cm x 18cm, Carton of 20 (German variant - ALLEVYN Silber Schaumverband Haftend)

ALLEVYN Ag Sacrum:

Size
Small, Carton of 10
Small, Carton of 3 (Spanish variant – ALLEVYN Plata Sacrum)
Small, Carton of 10
Large, Carton of 10
Large, Carton of 3 (Spanish variant – ALLEVYN Plata Sacrum)
Large, Carton of 10
Small Sacrum, carton of 10 (French variant – ALLEVYN S.Ag Adhesive)
Large Sacrum, carton of 10 (French variant – ALLEVYN S.Ag Adhesive)

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ALLEVYN Ag Non Adhesive:

Size
5cm x 5cm, Carton of 10
5cm x 5cm, Carton of 10
10cm x 10cm, Carton of 10
11cm x 11cm, Carton of 3 (Spanish variant – ALLEVYN Plata Non-adhesive)
10cm x 10cm, Carton of 10
15cm x 15cm, Carton of 10
15cm x 15cm, Carton of 3 (Spanish variant – ALLEVYN Plata Non-adhesive)
15cm x 15cm, Carton of 10
20cm x 20cm, Carton of 10
20cm x 20cm, Carton of 10
4.5cm x 5.5cm, Carton of 3 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
4.5cm x 5.5cm, Carton of 12 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
4.5cm x 5.5cm, Carton of 20 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
9cm x 11cm, Carton of 12 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
9cm x 11cm, Carton of 20 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
14cm x 16cm, Carton of 12 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)

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ALLEVYN Ag Non Adhesive (continued):

Size
14cm x 16cm, Carton of 20 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
19cm x 21cm, Carton of 12 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)
19cm x 21cm, Carton of 20 (German variant – ALLEVYN Silber Schaumverband Nicht Haftend)

ALLEVYN Ag Heel:

Size
Standard, Carton of 5
Standard, Carton of 3 (Spanish variant – ALLEVYN Plata Heel)
Standard, Carton of 7 (German variant – ALLEVYN Silber Schaumverband Ferse Nicht Haftend)
Standard, Carton of 10 (German variant – ALLEVYN Silber Schaumverband Ferse Nicht Haftend)

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ALLEVYN Ag Gentle:

Size
5cm x 5cm, Carton of 10
10cm x 10cm, Carton of 10
10cm x 20cm, Carton of 10
15cm x 15cm, Carton of 10
20cm x 20cm, Carton of 10
5cm x 5cm, Carton of 10
10cm x 10cm, Carton of 10
10cm x 20cm, Carton of 10
15cm x 15cm, Carton of 10
20cm x 20cm, Carton of 10

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ALLEVYN Ag Gentle Border:

Size
7.5cm x 7.5cm, Carton of 3
7.5cm x 7.5cm, Carton of 10
10cm x 10cm, Carton of 10
12.5cm x 12.5cm, Carton of 10
17.5cm x 17.5cm, Carton of 10
7.5cm x 7.5cm, Carton of 10
10cm x 10cm , Carton of 10
12.5cm x 12.5cm, Carton of 10
17.5cm x 17.5cm, Carton of 10

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Certificate History

Date	Reference Number	Action
27 September 2007	10088672	First issue. MHRA Consultation Number NB14607/0083
29 August 2008	10098806	ALLEVYN Ag Heel added to product list
20 March 2009	10103132	ALLEVYN Ag Gentle and ALLEVYN Ag Gentle Border added to product list. Minor wording changes to ALLEVYN Ag Adhesive and ALLEVYN Ag Non-Adhesive tables (inclusion of cm against first dimensions)
07 October 2009	10100541 10108701	Addition of French variants for ALLEVYN Ag Adhesive (66800605, 66800606) and ALLEVYN Ag Sacrum (66800607, 66800608). Shelf life extended to 2 years for ALLEVYN Ag, ALLEVYN Ag Adhesive and ALLEVYN Ag Sacrum. Tables updated to identify market-specific product codes
29 September 2010	10118235	Inclusion of alternative construction layer adhesive in ALLEVYN Ag Gentle Border
01 September 2011	10123738	SSD manufacturing site change; intermediate shelf life extended to 12 weeks; test method change for total silver in ALLEVYN Ag Gentle Border; removal of product codes from supplementary information

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02 December 2011	10130064	New sterilisation subcontractor for ALLEVYN Ag Gentle Border variants: Sterigenics, Belgium
30 March 2012	10135347	Change to packaging process conditions for Non-Adhesive variants (5cm x 5cm, 10cm x 10cm, 15cm x 15cm and 20cm x 20cm)
20 April 2012	10135427	Change to packaging process conditions for Non-Adhesive 20cm x 20cm variants
25 May 2012	10135643	Addition of German variants for ALLEVYN Ag Heel
25 July 2012	10136034	Addition of German variants for ALLEVYN Ag Adhesive
23 August 2012	10136819	Addition of German variants for ALLEVYN Ag Non-Adhesive
21 September 2012	10137166	Addition of German variants for ALLEVYN Ag Adhesive 9.5cm x 11cm and 17cm x 18cm
26 September 2012	10136950	Addition of S&N Medical (Suzhou) Ltd as alternative manufacturing site for ALLEVYN Ag Adhesive range.
	10135686	Certificate renewal

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Date	Reference Number	Action
31 May 2013	10141954 10142004 10142008	Extension to shelf-life for ALLEVYN Ag Heel to 36 months Addition of S&N Medical (Suzhou) Ltd as alternative manufacturing site for ALLEVYN Ag Gentle Border Addition of S&N Medical (Suzhou) Ltd as alternative manufacturing site for ALLEVYN Ag Adhesive (German variants)
06 September 2013	10143417	Addition of sample packs containing 3 dressings specific for the German market for ALLEVYN Ag Gentle Border (7.5cm x 7.5cm, Carton of 3), ALLEVYN Ag Adhesive (Silber Schaumverband Haftend – 7cm x 8cm, Carton of 3), and ALLEVYN Ag Non-Adhesive (Silber Schaumverband Nicht Haftend – 4.5cm x 5.5cm, Carton of 3)
25 April 2014	10146178	Addition of alternative manufacturing site, Smith & Medical (Suzhou) Ltd China for ALLEVYN Ag Heel

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Date	Reference Number	Action
22 September 2014	10150326	Change in primary packaging to paper/paper for all ALLEVYN Ag Adhesive and ALLEVYN Ag Sacrum product codes manufactured at Suzhou.
29 September 2014	10145763	Change to EtO pre-condition temperature and time for ALLEVYN Ag Gentle Border manufactured at the Hull facility. Rebranding of entire range; packaging material change for ALLEVYN Ag Non-Adhesive and ALLEVYN Ag Adhesive variants manufactured at the Hull facility
19 May 2015	10154774	Change to Smith & Nephew Suzhou's activities to include slitting of bulk top film for ALLEVYN AG Adhesive and ALLEVYN AG Gentle Border. Change to Smith & Nephew Suzhou's activities to include slitting and perforation of Wound Contact Layer for ALLEVYN AG Adhesive

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