

# 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  
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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2007-09-27**Date: **2020-04-01**Expiry Date: **2022-09-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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

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## Supplementary Information to CE 518880

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66800072	ALLEVYN Ag Adhesive	7.5cm x 7.5cm, Carton of 10 (International)	ALLEVYN Ag Adhesive is an antimicrobial absorbent dressing for the management, by secondary intention of chronic and acute full thickness, partial thickness or shallow granulating, exuding wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/ malignant wounds and surgically dehisced wounds. ALLEVYN Ag Adhesive may be used on infected wounds. Where the product is used on infected wounds the wounds should be treated as per local protocol.	III
66800073		7.5cm x 7.5cm, Carton of 10 (UK Only)		
66800074		10cm x 10cm, Carton of 10 (International)		
66800075		10cm x 10cm, Carton of 10 (UK Only)		
66800076		12.5cm x 12.5cm, Carton of 10 (International)		
66800078		12.5cm x 12.5cm, Carton of 10 (UK Only)		
66800080		17.5cm x 17.5cm, Carton of 10 (International)		
66800081		17.5cm x 17.5cm, Carton of 10 (UK Only)		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66801122	ALLEVYN Silber Schaumverband Haftend (German Variant)	7cm x 8cm, Carton of 12	ALLEVYN Silber Schaumverband haftend ist ein antimikrobieller absorbierender Wundverband zur Behandlung sekundär heilender, chronischer und akuter tiefer, halbtiefer oder flacher granulierender, exsudierender Wunden, wie zum Beispiel: Druckgeschwüre, Ulcera cruris, diabetische Ulcera, Verbrennungen, Entnahmestellen, wuchernde/maligne Wunden und klaffende Operationswunden. ALLEVYN Silber Schaumverband haftend kann auf infizierten Wunden verwendet werden. Wenn das Produkt auf infizierten Wunden verwendet wird, sollten die Wunden gemäß dem jeweiligen örtlichen Behandlungsprotokoll behandelt werden.	III
		7cm x 8cm, Carton of 20		
66801131		9.5cm x 11cm, Carton of 12		
66801123		9.5cm x 11cm, Carton of 20		
66801132		12cm x 13cm, Carton of 12		
66801124		12cm x 13cm, Carton of 20		
66801133		17cm x 18cm, Carton of 12		
66801125		17cm x 18cm, Carton of 20		
66801134		7cm x 8cm, Carton of 12		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66800092	ALLEVYN Ag Sacrum	17cm x 17cm (Small), Carton of 10 (International)	ALLEVYN Ag Adhesive is an antimicrobial absorbent dressing for the management, by secondary intention of chronic and acute full thickness, partial thickness or shallow granulating, exuding wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/ malignant wounds and surgically dehisced wounds. ALLEVYN Ag Adhesive may be used on infected wounds. Where the product is used on infected wounds the wounds should be treated as per local protocol.	III
66800094		17cm x 17cm (Small), Carton of 10 (UK Only)		
66800095		22cm x 22cm (Large), Carton of 10 (International)		
66800097		22cm x 22cm (Large), Carton of 10 (UK Only)		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66800082	ALLEVYN Ag Non Adhesive	5cm x 5cm, Carton of 10 (International)	ALLEVYN Ag Non-Adhesive is an antimicrobial absorbent dressing for the management, by secondary intention of chronic and acute full thickness, partial thickness or shallow granulating, exuding wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/malignant wounds and surgically dehisced wounds. ALLEVYN Ag Non-Adhesive may be used on infected wounds. Where the product is used on infected wounds the wounds should be treated as per local protocol.	III
66800083		5cm x 5cm, Carton of 10 (UK Only)		
66800084		10cm x 10cm, Carton of 10 (International)		
66800086		10cm x 10cm, Carton of 10 (UK Only)		
66800087		15cm x 15cm, Carton of 10 (International)		
66800089		15cm x 15cm, Carton of 10 (UK Only)		
66800090		20cm x 20cm, Carton of 10 (International)		
66800091		20cm x 20cm, Carton of 10 (UK Only)		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66801126	ALLEVYN Silber Schaumverband Nicht Haftend (German Variant)	4.5cm x 5.5cm, Carton of 12	ALLEVYN Silber Schaumverband nicht haftend ist ein absorbierender antimikrobieller Verband für die Behandlung sekundär heilender chronischer und akuter tiefer, flacher und oberflächlich granulierender und exsudierender Wunden wie zum Beispiel: Dekubitalulzera, venöse Ulzera, diabetische Ulzera, Verbrennungen, Spalthautentnahmestellen, wuchernde/maligne Wunden und chirurgisch geöffnete Wunden. ALLEVYN Silber Schaumverband nicht haftend kann bei infizierten Wunden eingesetzt werden. Wird das Produkt bei infizierten Wunden eingesetzt, sollte die Wunde gemäß lokalen klinischen Protokollen behandelt werden.	III
66801135		4.5cm x 5.5cm, Carton of 20		
66801127		9cm x 11cm, Carton of 12		
66801136		9cm x 11cm, Carton of 20		
66801128		14cm x 16cm, Carton of 12		
66801137		14cm x 16cm, Carton of 20		
66801129		19cm x 21cm, Carton of 12		
66801138		19cm x 21cm, Carton of 20		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66800098	ALLEVYN Ag Heel	Heel Dressing, Carton of 5	ALLEVYN Ag Non-Adhesive is an antimicrobial absorbent dressing for the management, by secondary intention of chronic and acute full thickness, partial thickness or shallow granulating, exuding wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/malignant wounds and surgically dehisced wounds. ALLEVYN Ag Non-Adhesive may be used on infected wounds. Where the product is used on infected wounds the wounds should be treated as per local protocol.	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66801130	ALLEVYN Silber Schaumverband	Heel Dressing, Carton of 7	ALLEVYN Silber Schaumverband nicht haftend ist ein absorbierender antimikrobieller Verband für die Behandlung sekundär heilender chronischer und akuter tiefer, flacher und oberflächlich granulierender und exsudierender Wunden wie zum Beispiel: Dekubitalulzera, venöse Ulzera, diabetische Ulzera, Verbrennungen, Spalthautentnahmestellen, wuchernde/maligne Wunden und chirurgisch geöffnete Wunden. ALLEVYN Silber Schaumverband nicht haftend kann bei infizierten Wunden eingesetzt werden. Wird das Produkt bei infizierten Wunden eingesetzt, sollte die Wunde gemäß dem jeweiligen örtlichen Behandlungsprotokoll behandelt werden.	III
66801139	Ferse Nicht Haftend (German Variant)	Heel Dressing, Carton of 10		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66800436	ALLEVYN Ag Gentle Border	7.5cm x 7.5cm, Carton of 10 (International)	ALLEVYN Ag Gentle Border is an absorbent antimicrobial dressing for the management, by secondary intention of chronic and acute full thickness, partial thickness or shallow granulating, exuding wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating / malignant wounds and surgically dehisced wounds. ALLEVYN Ag Gentle Border may be used on infected wounds. Where the product is used on infected wounds the wounds should be treated as per local protocol. ALLEVYN Ag Gentle Border can be used in conjunction with INTRASITE™ Gel for necrotic or sloughy wounds. ALLEVYN Ag Gentle Border is suitable for use on fragile skin.	III
66800460		7.5cm x 7.5cm, Carton of 10 (UK Only)		
66800437		10cm x 10cm, Carton of 10 (International)		
66800461		10cm x 10cm, Carton of 10 (UK Only)		
66800438		12.5cm x 12.5cm, Carton of 10 (International)		
66800462		12.5cm x 12.5cm, Carton of 10 (UK Only)		
66800439		17.5cm x 17.5cm, Carton of 10 (International)		
66800463		17.5cm x 17.5cm, Carton of 10 (UK Only)		

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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.

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Date	Reference Number	Action
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.
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.

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Date	Reference Number	Action
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.
31 May 2013	10141954	Extension to shelf-life for ALLEVYN Ag Heel to 36 months.
	10142004	Addition of S&N Medical (Suzhou) Ltd as alternative manufacturing site for ALLEVYN Ag Gentle Border.
	10142008	Addition of S&N Medical (Suzhou) Ltd as alternative manufacturing site for ALLEVYN Ag Adhesive (German variants).

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Date	Reference Number	Action
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.
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. Change to EtO pre-condition temperature and time for ALLEVYN Ag Gentle Border manufactured at the Hull facility.
29 September 2014	10145763	Rebranding of entire range; packaging material change for ALLEVYN Ag Non-Adhesive and ALLEVYN Ag Adhesive variants manufactured at the Hull facility.

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Date	Reference Number	Action
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.
01 June 2016	10162255	Addition of alternative manufacturing site (Smith & Nephew, Suzhou) for Allevyn Ag Non-Adhesive. Change to Smith & Nephew Suzhou's activities to include slitting and perforation of wound contact layer for Allevyn Ag Heel. Addition of double sterilisation and new sterilisation stacking configuration for Allevyn Ag Gentle Border (manufactured at Suzhou). Addition of alternative sterilization site for ALLEVYN Ag Heel (Suzhou CNNC Huadong Radiation Co).
22 September 2016	10165135	Addition of Smith & Nephew Medical (Hull) as an additional site for film extrusion for Allevyn Ag Adhesive and Allevyn Ag Non-Adhesive.

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Date	Reference Number	Action
22 November 2016	10166619	Addition of Smith & Nephew Medical (Hull) as an additional site for film extrusion for Allevyn Ag Gentle, Allevyn Ag Gentle border and Allevyn Ag Heel.
27 January 2017	10167667	Change from gamma tote irradiator to pallet irradiator for Allevyn Ag Adhesive and Allevyn Ag Gentle manufactured at the Hull site.
23 March 2017	10168191	Change of pad forming machine at Smith & Nephew Suzhou for Allevyn Ag Adhesive and Allevyn Ag Gentle Border.
20 April 2017	10169318	Addition of Smith & Nephew Suzhou for the slitting and perforating of the silicone wound contact layer for Allevyn Ag Gentle Border.
21 July 2017	8732616	Transfer of silicone coating process in-house to Hull site.
15 September 2017	8794589	Revalidation of conversion of ALLEVYN Ag Non-Adhesive 15x15cm product.

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Date	Reference Number	Action
22 September 2017	8744229	Certificate renewal.
02 November 2018	8872366	<p>Change to ALLEVYN Ag Gentle foam slitting process; Removal of product codes –</p> <p>ALLEVYN Ag Adhesive: 12.5cm x 12.5cm, Carton of 3 (Spanish variant – ALLEVYN Plata Adhesive), 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) and 17.5cm x 17.5cm, Carton of 10 (French variant – ALLEVYN S.Ag Adhesive).</p> <p>ALLEVYN Ag Sacrum: Small, Carton of 3 (Spanish variant – ALLEVYN Plata Sacrum), Small Sacrum, carton of 10 (French variant – ALLEVYN S.Ag Adhesive) and Large Sacrum, carton of 10 (French variant – ALLEVYN S.Ag Adhesive).</p> <p>Change from BI to Parametric release for sterilization of Allewyn Ag Gentle Border.</p>
27 February 2019	7779270	Traceable to NB 0086.

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## Certificate History

Date	Reference Number	Action
Current	3066884	Addition of second chamber for ETO Sterilization at Sterigenics Shanghai ETO Ltd for ALLEVYN Ag Gentle Border. Addition of EU Rep information to product labelling. Removal of discontinued products and update to the supplementary information table.

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**Supplementary Information to CE 518880** - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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**Date:** 26 November 2021

**Changes Approved:**

Date	Reference Number	Action
26 November 2021	3406937	Removal of donor site indication for ALLEVYN Ag Adhesive, ALLEVYN Silber Schaumverband Haftend and ALLEVYN Ag Sacrum.

26 November 2021

Smith & Nephew Medical Ltd  
 101 Hessle Road  
 Hull  
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 518880	93/42/EEC Annex II Section 4	3406937	Removal of donor site indication for ALLEVYN Ag Adhesive, ALLEVYN Silber Schaumverband Haftend and ALLEVYN Ag Sacrum.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack  
 Senior Vice President, Medical Devices