

**ATTESTATION / CERTIFICATE N° 32563 rev. 2**

Délivrée à Paris le 24 juillet 2018

Issued in Paris on July 24th, 2018

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production (limitée à l'obtention et au maintien de l'état stérile)

Approval of Production Quality Assurance System (related to securing and maintaining sterile conditions)

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

**Xodus Medical, Inc.**

**702 Prominence Dr.,**

**NEW KENSINGTON, PA, 15068 UNITED STATES**

Catégorie du(des) dispositif(s) / Device(s) category

**Light handles covers, transfer zones, needle counters, safety stops, syringes transfer cups, scalpel holders, cautery tip cleaner, skin markers, safety scalpel handles and shoulder suspension kit**

*Couvre-poignées légers, zones de transfert, compteurs à aiguille, butées de sécurité, gobelets de transfert de seringues, porte-scalpel, nettoyeur de cautère, marqueurs cutanés, poignées de bistouri de sécurité et kit de suspension d'épaule*

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000362-1-R, T000178-4-ADD, T000178-5-DOCA, le système d'assurance qualité - pour l'obtention et le maintien de l'état stérile - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced T000362-1-R, T000178-4-ADD, T000178-5-DOCA, the quality system - for the quality system for securing and maintaining sterile conditions - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : July 24th, 2018 (included)

Valable jusqu'au / Expiry date : July 30th, 2021 (included)



On behalf of the G-MED Certification Director

**Béatrice LYS**

G-MED Certification Technical Director

**Identification des dispositifs / Identification of devices**

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Flexible Light Handle Cover 1/pkg	60511	Is
Flexible Light Handle Cover 2/pkg	60512	
Flexible Light Handle Cover 3/pkg	60513	
Semi-Rigid Light Handle Cover	60711	
Semi-Rigid Light Handle Cover 2/pkg	60712	
Light Guard Rigid 1/pkg Sterile	60881	
Light Guard Rigid 1/pkg Sterile	60882	
Correct Site Marker; Sharpie Style	10400	
Correct Site Marker (small)	10402	
Correct Site Marker (small); w/ Ruler	10403	
Correct Site Marker (small); w/ Ruler and Labels	10404	
Permanent Marker; Round Pen Regular Tip (Purple)	10405	
Permanent Marker; Round Pen Regular Tip; w/ Labels	10406	
Permanent Marker; Round Pen Regular Tip; w/ Ruler and Labels	10407	

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**On behalf of the G-MED Certification Director  
 Béatrice LYS  
 G-MED Certification Technical Director**

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Correct Site Marker; Sharpie Style; w/ Ruler and Labels	10411	Is
Correct Site Marker; Sharpie Style; w/ Ruler	10412	
Permanent Marker; Round Pen Fine Tip (Blue)	10415	
Permanent Marker; Round Pen Fine Tip; w/ Labels	10416	
Permanent Marker; Round Pen Fine Tip; w/ Ruler and Labels	10417	
Roll Stop Skin Marker; Ruled Cap Regular Tip; w/ Ruler	10500	
Roll Stop Skin Marker; Ruled Cap Fine Tip; w/ Ruler	10511	
Roll Stop Skin Marker; Ruled Cap Regular Tip; w/ Ruler and Labels	10600	
Roll Stop Skin Marker; Ruled Cap Fine Tip; w/ Ruler and Labels	10611	
Roll Stop Skin Marker; Ruled Cap Regular Tip	10700	
Roll Stop Skin Marker; Ruled Cap Fine Tip (Blue)	10711	
Skin Marker; Round Pen Regular Tip	10715	
Skin Marker; Round Pen Fine Tip (Blue)	10716	
Skin Marker; Round Pen Regular Tip; w/ Ruler and Labels	10717	
Skin Marker; Round Pen Regular Tip; w/ Ruler	10718	

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Skin Marker; Round Pen Fine Tip (Blue); w/ Ruler and Labels	10719	Is
Skin Marker; Round Pen Fine Tip (Blue); w/ Ruler	10720	
Correct Site Skin Marker; Round Regular Tip	10725	
Correct Site Skin Marker; Round Regular Tip; w/ Ruler	10726	
Correct Site Skin Marker; Round Regular Tip; w/ Ruler and Labels	10727	
Medication Label Marker; Round Pen Regular Tip	10730	
Dual Tip Skin Marker; Regular and Fine Tip Gentian Violet	10731	
Dual Tip Skin Marker; Regular and Fine Tip Gentian Violet; w/ Ruler and Labels	10732	
Dual Tip Skin Marker; Regular and Fine Tip Gentian Violet; w/ Ruler	10733	
Dual Tip Marker; Regular Tip Gentian Violet and Regular Tip Permanent Ink	10735	
Dual Tip Marker; Regular Tip Gentian Violet and Regular Tip Permanent Ink; w/ Ruler and Labels	10736	
Dual Tip Marker; Regular Tip Gentian Violet and Regular Tip Permanent Ink; w/ Ruler	10737	
Skin Marker; Round Pen Extra Fine Tip (Green)	10746	
Skin Marker; Round Pen Extra Fine Tip (Green); w/ Ruler	10747	
Suture Holder	10651	

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Clear Plastix Box with labels, One Tab	70100	Is
Single Magnet 10-20 Count	70110	
1/2 Mag 1/2 Adhesive 10 Count	70119	
Double Magnet 20-40 Count	70120	
Double Magnet 30-60 Count	70130	
Single Magnet 15-30 Count	70131	
Double Magnet 60-120 Count	70160	
Single Magnet 30 Count	70161	
Double Magnet 20 Count with Blade Remover	70164	
Magnet/Foam Strips 30-60 Count	70211	
Magnet/Foam Strips 60-120 Count	70212	
Needle Counter 1/2 Adhesive 1/2 Foam Strips w/ Slits	70213	
1/2 Blank Magnet 1/2 Foam Strips 60-120 910 Box	70214	
1/2 Foam Strips 1/2 15 Count Magnet	70215	
1/2 Foam Strips 1/2 30 Count Magnet	70216	

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Needle Counter 40 Count - Adhesive, Foam Strips w/ 10 Slits	70222	Is
Needle Counter 40 Count - Adhesive, Foam Strips w/ 10 Slits	70222Y	
Needle Counter 20 Count - Adhesive, Foam Strips w/ 5 Slits	70223	
Double Foam Strips	70330	
1/2 Foam Strip w/ Magnet	70331	
Double Foam Strips 60-120 Count	70360	
1/2 Adhesive 1/2 Foam Strips 30 Count	70361	
Foam Strip/Adhesive	70362	
10 Count Foam Block	70400	
Needle Counter Foam Block/Magnet 10 Count	70410	
Adhesive/Foam Block 10 Count	70411	
Magnet/Foam Block 20-40 Count	70412	
1/2 Magnet 1/2 Foam Block 20-40 Count w/ Blade Remover	70414	
Yellow Needle Counter Magnet/Foam Block 20-40 Count w/ Blade Remover	70414Y	
Needle Counter 1/2 White Magnet / 1/2 Foam Block 20-40 Count	70415	

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Large 10 Count Foam Block	70417	Is
Needle Counter Large 10 Count 1/2 Magnet 1/2 Foam Block	70418	
Needle Counter Large 10 Count 1/2 Adhesive 1/2 Foam Block	70419	
1/2 Foam Block 20 Count	70420	
Adhesive/Foam Block 20-40 Count	70423	
Adhesive/Foam 20-40 Count	70424	
Double Foam Block 40-80 Count	70440	
Double Foam Block 20-40 Count	70441	
Foam Strip/Magnet 30 Count Blade Remover	70455	
Double Foam Strips 30-60 Count with Blade Remover	70456	
Double Magnet w/ Blade Remover 30 Count	70464	
Double 15 Count Magnet 1/2 20 Count Foam Block	70465	
Double Magnet 1/2 Foam Block Blade Remover 20-40 Count	70470	
1/2 Foam Block Double Magnet 20 Count	70481	
Double Magnet w/o Numbers Double Foam Block 40-80 Count	70482	

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Needle Counter 1/2 Magnet 1/2 Foam Block 40-80 Count	70512	Is
Needle Counter 1/2 Magnet 1/2 Foam Block 40-80 Count w/ Blade Remover	70514	
Needle Counter w/ Blade Remover, Yellow Magnet/Foam Block 40-80 Count	70514Y	
Needle Counter 1/2 White Magnet 1/2 Foam Block 40-80 Count	70515	
Attached 1/2 Foam Block 40 Count	70522	
Adhesive/Foam Block 40-80 Count	70523	
1/2 Foam Block 1/2 Adhesive 40-80 Count w/ Blade Remover	70524	
1/2 Foam Block 40 Count	70525	
Foam Block/Magnet 40 Count	70529	
1/2 Magnet 1/2 Foam Strips 80 Count with Blade Remover	70555	
Double Foam Strips 60-120 Count with Blade Remover	70556	
Double Magnet 60 Count (Deep Box)	70560	
Double Magnet w/o Numbers	70561	
Blade Remover Double 60 Count Magnet	70564	
Double Blank Magnet/Single Foam Block 40 Count w/ Blade Remover	70570	

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Double 30 Count Magnet/Single Foam Block 40 Count w/ Blade Remover	70571	Is
Double Foam Block 80-160 Count	70580	
Double 30 Count Magnet/40 Count Foam	70581	
Double Magnet w/o Numbers Double Foam Block 80-160 Count	70582	
Double Magnet Strips 60 Count	70660	
Double Magnet Strips 60 Count with Blade Remover	70661	
1/2 White Magnet 1/2 Foam Strips 30 Count	70711	
Double Magnet White 30 Count	70730	
Double White Magnet w/o Numbers	70731	
1/2 White Magnet 1/2 Foam Strips 60 Count	70742	
Double Magnet White	70760	
Double White Magnet 60-120 Count	70761	
Clear Top 10 Count Magnet	70810	
Clear Top w/ 1/2 Foam Strips 15 Count	70830	
Clear Top 15 Count Magnet	70831	

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Clear Top 30 Count Magnet	70861	Is
Single Magnet 10-20 Count w/ Blade Remover	70870	
Single Magnet 15-30 Count w/ Blade Remover	70871	
Single Magnet 30-60 Count w/ Blade Remover	70872	
1/2 Magnet 1/2 Adhesive 10 Count w/ Blade Remover	70873	
Double Magnet Strips 60 Count w/ Blade Remover	70875	
Double Magnet 20-40 Count w/ Blade Remover	70880	
1/2 Foam Stirps 1/2 Black Magnet 30-60 Count w/ Blade Remover	70881	
1/2 Foam Stirps 1/2 Black Magnet 60-120 Count w/ Blade Remover	70882	
Double Foam Strips 30-60 Count with Blade Remover	70883	
Double Foam Strips 60-120 Count with Blade Remover	70884	
Double Magnet 30-60 Count w/ Blade Remover	70890	
Double Magnet 60-120 Count w/ Blade Remover	70900	
Blank Double Magnet Small	70930	
Double Magnet w/o Numbers 15-30 Count w/ Blade Remover	70931	

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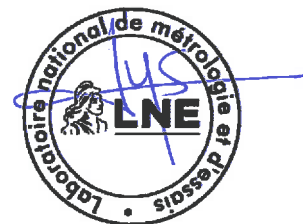
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Blank Double Magnet 60 Count	70960	Is
Double Magnet w/o Numbers White 30-60 Count w/ Blade Remover	70961	
Scalpel Holder	20220	
Safety Stop w/ Plastic Case Temp. Sharps Holder	10670	
Sharps Cup Sterile	80100	
Shoulder Suspension Kit	90403	
Sharps Saf-T Transfer Zone Non-Magnetic 32/case	80300	
Sharps Saf-T Transfer Zone w/o Tray	80400	
Single Use Non-Magnetic Zone 16" x 10"	80700	
Single Use Magnetic Zone 16" x 10"	80710	
Single Use Magnetic Transfer Zone w/ Tray 16" x 10"	80715	
Single Use Magnet Transfer Zone 16" x 20"	80720	
Single Use Magnetic Transfer Zone w/ Tray 16" x 20"	80725	
Single Use Magnetic Transfer Zone 3" x 4 1/2"	80730	
Cautery Tip Cleaner	30500	

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Safety Scalpel #3 Handle Stainless Steel	90000	Is
Safety Scalpel #3 Long Handle Stainless Steel	90001	

**Ce certificat couvre les sites suivants :**  
*This certificate covers the following sites:*

Xodus Medical, Inc.  
702 Prominence Dr  
New Kensington, PA 15068  
USA

\*\*\*\*

**Activités effectuées en ce site / Activities performed on this site:**

**Siège social, Fabrication et Contrôle Final**  
*Headquarters, Manufacturing and Final Control*

\*\*\*\*

Xodus Medical, Inc.  
204 Myles Drive  
New Kensington, PA 15068  
USA

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**Contrôle Final**  
*Final Control*

\*\*\*

**2 sites / 2 sites**

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