

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

Couvre poignée de lumière, zones de transit, compteurs d'aiguille, block de sécurité, gobelet de transfert de seringues, étuis à bistouris, crayons dermographiques et kit de suspension d'épaule

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

Voir document complémentaire GMED / See GMED additional document

n° 37995

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000362, 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.

GMED certifies that, on the basis of the results contained in the file referenced T000362, 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 : February 25th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



DocuSigned by:

Beatrice Lys

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On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 37995 rev. 1 atteste de la validité du certificat CE n° 32563 rev. 3 au regard des informations listées ci-dessous.

This GMED additional document N° 37995 rev. 1 attests to the validity of CE certificate n° 32563 rev. 3 with regard to the information listed below.

Fabricant / Manufacturer: **Xodus Medical, Inc.**
702 Prominence Dr.
New Kensington, PA 15068 United States

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	
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	

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Catherine Holzmann
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On behalf of the President
Catherine HOLZMANN
Department Manager

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>
Correct Site Marker (small); w/ Ruler	10403	Is
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	
Correct Site Marker; Sharpie Style; w/ Ruler and Labels	10411	
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	

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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>
Skin Marker; Round Pen Regular Tip; w/ Ruler and Labels	10717	Is
Skin Marker; Round Pen Regular Tip; w/ Ruler	10718	
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	
Clear Plastic Box with labels, One Tab	70100	Is

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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>
Single Magnet 10-20 Count	70110	Is
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	
1/2 Foam Strips 1/2 15 Count Magnet	70215	
1/2 Foam Strips 1/2 30 Count Magnet	70216	
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	
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	

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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>
1/2 Magnet 1/2 Foam Block 20-40 Count w/ Blade Remover	70414	Is
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	
Needle Counter Large 10 Count 1/2 Magnet 1/2 Foam Block	70418	
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 Magnet w/ Blade Remover 30 Count	70464	
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	
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	

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Adhesive/Foam Block 40-80 Count	70523	Is
1/2 Foam Block 1/2 Adhesive 40-80 Count w/ Blade Remover	70524	
Double Magnet 60 Count (Deep Box)	70560	
Blade Remover Double 60 Count Magnet	70564	
Double Blank Magnet/Single Foam Block 40 Count w/ Blade Remover	70570	
Double 30 Count Magnet/Single Foam Block 40 Count w/ Blade Remover	70571	
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	
1/2 White Magnet 1/2 Foam Strips 30 Count	70711	
Double Magnet White 30 Count	70730	
Double White Magnet w/o Numbers	70731	
Double Magnet White	70760	
Double White Magnet 60-120 Count	70761	
Clear Top 10 Count Magnet	70810	
Clear Top 15 Count Magnet	70831	
Clear Top 30 Count Magnet	70861	
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	
Double Magnet 20-40 Count w/ Blade Remover	70880	
Double Magnet 30-60 Count w/ Blade Remover	70890	

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Double Magnet 60-120 Count w/ Blade Remover	70900	Is
Blank Double Magnet 60 Count	70960	
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	
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	

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Xodus Medical, Inc. 702 Prominence Dr, New Kensington, PA 15068	Siège social, Fabrication et Contrôle Final <i>Headquarters, Manufacturing and Final Control</i>
Xodus Medical, Inc. 204 Myles Drive New Kensington, PA 15068 USA	Contrôle Final <i>Final Control</i>

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Modifications / Modifications

Identification des modifications apportées au certificat CE n° 32563 rev. 3:
Identification of the modifications made to the CE certificate n° 32563 rev. 3:

Modifications / Modifications	Dossier(s) / File(s) N°	Date / Date
Nouvelle référence de rapport dans le cadre du maintien de la certification <i>New file reference in the framework of the maintenance of the certification</i>	T001282_P1-R	4 mars 2021 <i>March 4, 2021</i>

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