

**DECLARATION OF CONFORMITY
TO REGULATION (EU) 2017 / 745 OF THE EUROPEAN
PARLIAMENT AND THE COUNCIL OF 5, APRIL 2017
CONCERNING MEDICAL DEVICES**



MANUFACTURER:

VISCOT MEDICAL, LLC
32 WEST STREET
EAST HANOVER, NJ 07936

WE VISCOT MEDICAL, LLC HEREBY DECLARE UNDER SOLE RESPONSIBILITY THAT THE DEVICES LISTED IN ATTACHED APPENDIX 1 COMPLY WITH THE PROVISIONS OF THE REGULATION (EU) 2017 / 745. THE DEVICES ARE CLASS 1 FOLLOWING RULE 1 OF ANNEX VIII OF REGULATION (EU) 2017 / 745.

MEDICAL DEVICE: STERILE MARKERS (APPENDIX 1)
UMDNS NUMBER 12443

BASIC UDI-DI: 08481060VIS500F9

CLASSIFICATION - ANNEX VIII: CLASS 1S, CHAPTER III, 4.1, RULE 1

CONFORMITY ASSESSMENT ROUTE: ANNEX V

WE, VISCOT MEDICAL, LLC, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF (EU) 2017 / 745 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL OF 5, APRIL 2017 CONCERNING MEDICAL DEVICES.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

- 1.) BS EN ISO 13485:2016 MEDICAL DEVICES- QUALITY MANAGEMENT SYSTEMS-REQUIREMENTS FOR REGULATORY PURPOSES
- 2.) BS EN ISO 15223-1 SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELING AND INFORMATION TO BE SUPPLIED
- 3.) ANSI/AAMI/ISO 11137-1 REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

NOTIFIED BODY: BSI
SAY BUILDING
JOHN M. KEYNESPLEIN 9
1066 EP AMSTERDAM,
THE NETHERLANDS

IDENTIFICATION NUMBER

CE 2797

(EC) CERTIFICATE: CERTIFICATE NUMBER: MDR 773827 R000 (EXPIRES: 10/25/2027)

EC REP

EUROPEAN REPRESENTATIVE: P.J. DAHLHAUSEN & CO. GMBH
50996 KOLN, GERMANY

START OF CE-MARKING: OCTOBER 4, 2002

CERTIFICATE EXPIRATION: OCTOBER 25, 2027

PLACE, DATE OF DECLARATION:

EAST HANOVER, NEW JERSEY 07936 USA
NOVEMBER 4, 2022

SIGNATURE:


NAME: GARY PIERINGER
POSITION: PRESIDENT

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APPENDIX 1

<u>Marker Part Number</u>	<u>Description</u>
1400	Viscot Precision Surgical Marker, Regular Tip, Traditional Ink
1402	Viscot Precision Surgical Marker, Ultra Fine Tip, Traditional Ink
1404	Viscot Precision Surgical Marker, Broad Tip, Traditional Ink
1422	Viscot Surgical Marker, Dual Tip (Regular Tip + Traditional Ink and Fine Tip + Permanent Utility Ink)
1424	Viscot BlephMarker®, Twin Tip (Two Ultra Fine Tips), Traditional Ink
1425	Viscot Surgical Marker, Twin Tip (Regular Tip & Ultra Fine Tip), Traditional Ink
1436	Viscot Value Surgical Marker, Ultra Fine Tip, Traditional Ink
1437	Viscot Value Surgical Marker, Regular Tip, Traditional Ink
1438	Viscot Value Surgical Marker, Regular Tip, Traditional Ink (Tail on Cap)
1447XL	Viscot XL Skin Marker, Regular Tip, Prep Resistant Ink
1448XL	Viscot XL Skin Marker, Ultra Fine Tip, Prep Resistant Ink
1449XL	Viscot XL Skin Marker, Bold Tip, Prep Resistant Ink
1450XL	Viscot XL Skin Marker Mini, Regular Tip, Prep Resistant Ink
1451	Viscot Surgical Marker Mini, Regular Tip, Traditional Ink
1456XL	Viscot XL Skin Marker Mini, Ultra Fine Tip, Prep Resistant Ink
1460	Viscot Standard Surgical Marker, Regular Tip, Traditional Ink