

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



MANUFACTURER:

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

MEDICAL DEVICE:

*STERILE MARKERS
UMDNS NUMBER 12443*

CLASSIFICATION - ANNEX IX:

CLASS 1, SECTION III, 1.1, 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 COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

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

- 1.) BS EN ISO 13485:2012 MEDICAL DEVICES- QUALITY MANAGEMENT SYSTEMS-REQUIREMENTS FOR REGULATORY PURPOSES
- 2.) BS EN ISO 15223-1:2012 SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELLING AND INFORMATION TO BE SUPPLIED
- 3.) ANSI/AAMI/ISO 11137-1:2015 REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

NOTIFIED BODY:

*BSI GROUP, KITEMARK COURT,
DAVY AVENUE,
KNOWLHILL,
MILTON KEYNES,
MK5 8PP
UNITED KINGDOM*

IDENTIFICATION NUMBER

CE 0086

(EC) CERTIFICATE:

EC CERTIFICATE NUMBER CE 68334



EUROPEAN REPRESENTATIVE:

*P.J. DAHLHAUSEN & Co. GMBH
50996 KOLN, GERMANY*

START OF CE-MARKING:

OCTOBER 4, 2002

PLACE, DATE OF DECLARATION:

*EAST HANOVER, NEW JERSEY 07936 USA
FEBRUARY 23, 2016*

SIGNATURE:

*NAME: GARY DIERINGER
POSITION: PRESIDENT*