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 13485:2016 MEDICAL DEVICES- QUALITY MANAGEMENT SYSTEMS-REQUIREMENTS FOR REGULATORY PURPOSES
2.) BS EN ISO 15223-1 SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELLING 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:	*EC CERTIFICATE NUMBER CE 68334 (EXPIRES: 10/3/2022)*
EC REP 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 13, 2020

SIGNATURE: _____

NAME: GARY PIERINGER
POSITION: PRESIDENT