

## Deklaracja zgodności

Firma Anspach Effort, Inc. (4500 Riverside Drive, Palm Beach Gardens, Floryda 33410, USA) niniejszym deklaruje na swoją wyłączną odpowiedzialność, że wyrób medyczny/rodzina wyrobów [narzędzia do dyssekcji] (klasa [IIa]) spełniają wszystkie wymagania:

dyrektywy Rady Europejskiej 93/42/EWG (obowiązującej).

Niniejszym deklarujemy zgodność ww. wyrobu medycznego/rodziny wyrobów z dyrektywą Rady 93/42/EWG, załącznik I, w tym ze stosownymi normami wskazanymi na liście kontrolnej zasadniczych wymogów oraz w załączniku V i VII.

Ww. wyrób medyczny/rodzinę wyrobów po raz pierwszy opatrzono oznakowaniem CE w roku [1 lutego 2005 r.].

Załączono listę wyrobów medycznych objętych niniejszą deklaracją zgodności.

Przedstawiciel w WE:	Jednostka notyfikowana (załącznik V):
DePuy Ireland UC	BSI Group The Netherlands B.V.
Loughbeg, Ringaskiddy Co.Cork, Irlandia	Say Building John M. Keynesplein 9 1066 EP Amsterdam Niderlandy
Tel.: +353 214914278 Faks: +353 214914199	Tel.: +31 20 346 07 80
	Numer identyfikacyjny jednostki notyfikowanej 2797
	Certyfikat CE: CE 541784 Ważny do: 27 listopada 2023 r.

**Producent:**

Anspach Effort, Inc.  
4500 Riverside Drive  
Palm Beach Gardens, FL 33410  
USA

**Denise Haley**

Denise Haley  
Starsza specjalistka ds. rejestracji wyrobów

**Tamara West**

Tamara J. West  
Kierownik ds. rejestracji wyrobów

Data  
Podpisane cyfrowo przez Denise Haley  
DN: c=US, o=JW, ou=Subskrybenci, cn=Denise Haley, 09.2342.19200300.100.1.1=702275366  
Uzasadnienie: zatwierdzam niniejszy dokument.  
Data: 2021.07.07 08:43:30 -04'00'  
Wersja Adobe Acrobat DC: 2015.006.30527

Data  
Podpisane cyfrowo przez Tamara West  
DN: c=US, o=JW, ou=Subskrybenci, cn=Tamara West, 09.2342.19200300.100.1.1=1030416  
Uzasadnienie: zatwierdzam niniejszy dokument.  
Data: 2021.07.07 11:01:05 -04'00'  
Wersja Adobe Acrobat DC: 2015.006.30527

*Niniejsza deklaracja zgodności z europejską dyrektywą dotyczącą wyrobów medycznych 93/42/EWG została ponownie wydana i podpisana ze względów administracyjnych.*

*Potwierdzamy, że produkty te uwzględnione zostały w aktualnej deklaracji zgodności CE przed datą*

*wejścia w życie (26 maja 2021 r.) rozporządzenia (UE) 2017/745 i mogą nadal być wprowadzane do obrotu zgodnie z art. 120 Przepisy przejściowe rozporządzenia.*

## Declaration of Conformity

The Anspach Effort, Inc. (4500 Riverside Drive, Palm Beach Gardens, Florida 33410, USA) hereby declares under its sole responsibility that the medical device/device family [Dissection Tools] (Class [IIa]) meets all the provisions of the:

European Council Directive 93/42/EEC (which apply).

We hereby declare the conformity of above mentioned medical device/device family according to the European Council Directive 93/42/EEC, Annex I including applicable standards as indicated in the Essential Requirements Checklist and Annex V and VII.

The above mentioned medical device/device family was initially CE released in the year [01 February 2005].

The list of medical devices covered by this Declaration of Conformity is attached.

EC Representative:	Notified Body (Annex V):
DePuy Ireland UC  Loughbeg, Ringaskiddy Co.Cork, Ireland  Tel: +353 214914278 Fax: +353 214914199	BSI Group The Netherlands B.V.  Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands  Tel: +31 20 346 07 80  Notified Body Identification Number 2797  CE Certificate: CE 541784 Valid Until: 27 November 2023

**Manufacturer:**

The Anspach Effort, Inc.  
4500 Riverside Drive  
Palm Beach Gardens, FL 33410  
USA

**Denise Haley**

Denise Haley  
Sr. Regulatory Affairs Specialist

**Tamara West**

Tamara J. West  
Regulatory Affairs Manager

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Reason: I am approving this document.  
Date: 2023.07.27 11:01:05 -0400  
E-mail: tamara@anpach.com

Date

*This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes.*

*We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.*

**Product List**

Catalog No.	Description	GMDN
BLA-1	1.85MM X 16MM FLUTED ROUTER	46269
BLA-10	9.5MM FLUTED DRUM	46269
BLA-15	3.2MM FLUTED CARBIDE SIDE CUTR	46269
BLA-2	2.15MM X 25.4MM FLUTED ROUTER	46269
BLA-5	5MM FLUTED BALL	46269
BLA-51	6.4MM FLUTED CYLINDRIC CARBIDE	46269
BLA-9	6.4MM FLUTED DRUM	46269
BLU-10	9.5MM FLUTED DRUM	46269
BLU-32	7.5MM FLUTED ACORN	46269
BLU-51	6.4MM FLUTED CYLINDRICAL CARBIDE	46269
BLU-7	7MM FLUTED BALL	46269
BLU-8	3MM FLUTED MATCHSTICK	46269
BLU-8-18	1.8MM FLUTED MATCHSTICK	46269
BLU-8D-32	3.2MM DIAMOND MATCHSTICK	46269
BLU-8D-32C	3.7MM COARSE DIAMOND MTCHSTCK	46269
BLU-8-M	3MM FLUTED MATCHSICK (LESS AGGRESSIVE)	46269
BLU-9	6.4MM FLUTED DRUM	46269
BLU-9DCX	6.8X10.6MM XCOARSE DIAMND DRUM	46269
BLU-CS5	5MMX14MM FLUTED DRUM(SIDE CUT)	46269
BLU-LS9-35	3.5MM X 19.8MM FLUTED DRUM	46269
BLU-LS9-5	4.7MM X 20MM FLUTED DRUM	46269
BLU-LS9-5E	4.7MMX20MM FLUTD DRM(SIDE CUT)	46269
CDA-1R	1.2MM X 12.8MM FLUTED ROUTER	46269
GOL-2	2.5MM X 25.4MM FLUTED ROUTER	46269
GOL-2S	2.47MM X 30.3MM SPIRAL ROUTER	46269
GRE-1	1.85MM X 16MM FLUTED ROUTER	46269
GRE-1S	2.15MM X 22MM SPIRAL ROUTER	46269
GREY-471-25	1.0MM DRILL FOR 1.25MM SCREW	46269
GREY-471-50	1.1MM DRILL FOR 1.5MM SCREW	46269
GREY-MIA20-4	4MM FLUTED BALL	46269
GREY-MIA20-7	7MM FLUTED BALL, MIA 20CM	46269
LHD-6B-M	6MM FLUTED BALL	46269
MA10-05SD	.5MM DIAMOND BALL, 10CM	46269
MA10-08SD	.8MM DIAMOND BALL, 10CM	46269

Catalog No.	Description	GMDN
MA10-15SB	1.5MM FLUTED BALL, 10CM	46269
MA10-1SB	1MM FLUTED BALL, 10CM	46269
MA10-25SB	2.5MM FLUTED BALL, 10CM	46269
MA10-2SB	2MM FLUTED BALL, 10CM	46269
MA10-2SD	2MM DIAMOND BALL, 10 CM	46269
MA10-3SB	3MM FLUTED BALL, 10CM	46269
MA10-3SD	3MM DIAMOND BALL, 10CM	46269
MA10-4D	4MM DIAMOND BALL, 10CM	46269
MA10-8N	2.3MM FLUTED MATCHSTICK, 10CM	46269
MA10-8N-18	1.8MM FLUTED MATCHSTICK, 10CM	46269
MA10-8NS	3MM FLUTED MATCHSTICK, 10CM	46269
MA10-8NSDC	3MM COARSE DMND MATCHSTCK,10CM	46269
MA15-15SD	1.5MM STD DIAMOND BALL, 15CM	46269
MA15-2SB	2MM FLUTED BALL, 15CM	46269
MA15-2SD	2MM DIAMOND BALL, 15CM	46269
MA15-3SB	3MM FLUTED BALL, 15CM	46269
MA15-3SD	3MM DIAMOND BALL, 15CM	46269
MA15-4D	4MM DIAMOND BALL, 15CM	46269
MA15-4DC	4MM COARSE DIAMOND BALL, 15 CM	46269
MA15-8N	2.3MM FLUTED MATCHSTICK, 15CM	46269
MA15-8N-18	1.8MM FLUTED MATCHSTICK, 15CM	46269
MA15-8NS	3MM FLUTED MATCHSTICK, 15CM	46269
MA15-8NSDC	3MM CRSE DMND MTCHSTCK,15CM	46269
MA19-15SD	1.5MM DIAMOND BALL, 19CM	46269
MA19-2SB	2MM FLUTED BALL, 19CM	46269
MA19-2SD	2MM DIAMOND BALL, 19CM	46269
MA19-3SB	3MM FLUTED BALL, 19CM	46269
MA19-3SD	3MM DIAMOND BALL, 19CM	46269
MA19-4B	4MM FLUTED BALL, 19CM	46269
MA19-4D	4MM DIAMOND BALL, 19CM	46269
MA19-8N	2.3MM FLUTED MATCHSTICK, 19CM	46269
MA19-8N-18	1.8MM FLUTED MATCHSTICK, 19CM	46269
MA19-8NS	3MM FLUTED MATCHSTICK, 19CM	46269
MA19-8NSDC	3MM COARSE DIAMOND MATCHSTICK, 19CM	46269
MIA16-5DRM	5MM X 8.4MM FLUTED DRUM FOR MIA16	46269
MRA-8L	2.3MM X 4.5MM FLUTED MATCHSTIK	46269
MRA-8M	2.3MM X 4.5MM FLUTED MATCHSTIK	46269

Catalog No.	Description	GMDN
MRA-8S	2.3MM X 4.5MM FLUTED MATCHSTIK	46269
ORNG-1	11.1MM FLUTED ROUTER	46269
ORNG-1275	1.2MM X 7.5MM TWIST DRILL	46269
ORNG-8-18	1.8MM FLUTED MATCHSTICK	46269
QD11-1R	1.4MM X 12.8MM FLUTED ROUTER	46269
QD11-1SB	1MM FLUTED BALL	46269
QD11-1SD	1MM DIAMOND BALL	46269
QD11-2SB	2MM FLUTED BALL	46269
QD11-2SD	2MM DIAMOND BALL	46269
QD11-3SB	3MM FLUTED BALL	46269
QD11-3SD	3MM DIAMOND BALL	46269
QD11-3SDC	3MM COARSE DIAMOND BALL	46269
QD11-4B	4MM FLUTED BALL	46269
QD11-4BA-A	4MM X 11MM FLUTED BARREL, 14 FLUTES	46269
QD11-4D	4MM DIAMOND BALL	46269
QD11-4DC	4MM COARSE DIAMOND BALL	46269
QD11-4DX	4MM EXTRA COARSE DIAMOND BALL	46269
QD11-4DX-20	4MM X-COARSE DIAMOND BALL, 20/30 GRIT	46269
QD11-4OV	4MM X 8MM FLUTED OVAL	46269
QD11-4OVDC	4MM X 8MM COARSE DIAMOND OVAL	46269
QD11-5B	5MM FLUTED BALL	46269
QD11-5B-12F	5MM FLUTED BALL, 12 FLUTES	46269
QD11-5B-A	5MM FLUTED BALL, LESS AGGRESSIVE	46269
QD11-5BA-A	5MM X 11.3MM FLUTED BARREL	46269
QD11-5D	5MM DIAMOND BALL	46269
QD11-5DC	5MM COARSE DIAMOND BALL	46269
QD11-5DRM	5MM X 8.4MM FLUTED DRUM	46269
QD11-5DX	5MM EXTRA COARSE DIAMOND BALL	46269
QD11-5OV	5MM X 10MM FLUTED OVAL	46269
QD11-6B	6MM FLUTED BALL	46269
QD11-6BA-A	6MM X 11.3MM FLUTED BARREL	46269
QD11-6D	6MM DIAMOND BALL	46269
QD11-6DC	6MM COARSE DIAMOND BALL	46269
QD11-6DX	6MM EXTRA COARSE DIAMOND BALL	46269
QD11-7B	7MM FLUTED BALL	46269
QD11-8N	2.3MM FLUTED MATCHSTICK	46269
QD11-8N-18	1.8MM FLUTED MATCHSTICK	46269

Catalog No.	Description	GMDN
QD11-8ND	2.5MM DIAMOND MATCHSTICK	46269
QD11-8NS	3MM FLUTED MATCHSTICK	46269
QD11-8NSDC	3.2MM COARSE DIA MATCHSTICK	46269
QD11-8NS-M	3MM FLUTED MATCHSTICK, LESS AGGRESSIVE	46269
QD14-1SD	1MM DIAMOND BALL	46269
QD14-2SD	2MM DIAMOND BALL	46269
QD14-3SB	3MM FLUTED BALL	46269
QD14-3SD	3MM DIAMOND BALL	46269
QD14-47DRM	4.7MM X 8MM FLUTED DRUM	46269
QD14-4B	4MM FLUTED BALL	46269
QD14-4BA	4MM X 8MM FLUTED BARREL	46269
QD14-4D	4MM DIAMOND BALL	46269
QD14-4DC	4MM COARSE DIAMOND BALL	46269
QD14-4OV	4MM X 8MM FLUTED OVAL	46269
QD14-5B	5MM FLUTED BALL	46269
QD14-5B-A	5MM FLUTED BALL, LESS AGGRESSIVE	46269
QD14-5D	5MM DIAMOND BALL	46269
QD14-5DC	5MM COARSE DIAMOND BALL	46269
QD14-6B	6MM FLUTED BALL	46269
QD14-6D	6MM DIAMOND BALL	46269
QD14-6DX	6MM EXTRA COARSE DIAMOND BALL	46269
QD14-8N	2.3MM FLUTED MATCHSTICK	46269
QD14-8N-18	1.8MM FLUTED MATCHSTICK	46269
QD14-8ND	2.5MM DIAMOND MATCHSTICK	46269
QD14-8NS	3MM FLUTED MATCHSTICK	46269
QD14-8NSDC	3.2MM COARSE DIAMOND MATCHSTICK	46269
QD8-05B	0.5MM FLUTED BALL	46269
QD8-05SD	.5MM DIAMOND BALL	46269
QD8-15SB	1.5MM FLUTED BALL	46269
QD8-15SD	1.5MM DIAMOND BALL	46269
QD8-15SDC	1.5MM COARSE DIAMOND BALL, 120/140 GRIT	46269
QD8-1R	1.4MM X 12.8MM FLUTED ROUTER	46269
QD8-1SB	1MM FLUTED BALL	46269
QD8-1SD	1MM DIAMOND BALL	46269
QD8-25SB	2.5MM FLUTED BALL	46269
QD8-25SD	2.5MM DIAMOND BALL	46269
QD8-25SDC	2.5MM CRSE DIAMOND BALL	46269

Catalog No.	Description	GMDN
QD8-2SB	2MM FLUTED BALL	46269
QD8-2SD	2MM DIAMOND BALL	46269
QD8-2SDC	2MM COARSE DIAMOND BALL	46269
QD8-35SD	3.5MM DIAMOND BALL	46269
QD8-35SDC	3.5MM CRSE DIAMOND BALL	46269
QD8-3SB	3MM FLUTED BALL	46269
QD8-3SD	3MM DIAMOND BALL	46269
QD8-3SD-100	3MM DIAMOND BALL, STD 100/120	46269
QD8-3SDC	3MM COARSE DIAMOND BALL	46269
QD8-4B	4MM FLUTED BALL	46269
QD8-4D	4MM DIAMOND BALL	46269
QD8-4DC	4MM COARSE DIAMOND BALL	46269
QD8-4DX	4MM EXTRA COARSE DIAMOND BALL	46269
QD8-4OV	4MM X 8MM FLUTED OVAL	46269
QD8-5B	5MM FLUTED BALL	46269
QD8-5BA	5MM X 10MM FLUTED BARREL	46269
QD8-5B-C-10F	5MM CARBIDE FLUTED BALL, 10 FLUTES	46269
QD8-5D	5MM DIAMOND BALL	46269
QD8-5D-2	5MM DIAMOND BALL, 2MM SHAFT EXPOSURE	46269
QD8-5DC	5MM COARSE DIAMOND BALL	46269
QD8-5DX	5MM EXTRA COARSE DIAMOND BALL	46269
QD8-5OV	5MM X 10MM FLUTED OVAL	46269
QD8-6B	6MM FLUTED BALL	46269
QD8-6D	6MM DIAMOND BALL	46269
QD8-6DC	6MM COARSE DIAMOND BALL	46269
QD8-6DX	6MM EXTRA COARSE DIAMOND BALL	46269
QD8-7B	7MM FLUTED BALL	46269
QD8-8N	2.3MM FLUTED MATCHSTICK	46269
QD8-8N-18	1.8MM FLUTED MATCHSTICK	46269
QD8-8ND	2.5MM DIAMOND MATCHSTICK	46269
QD8-8NS	3MM FLUTED MATCHSTICK	46269
RED-2	2.15MM X 25.4MM FLUTED ROUTER	46269
RED-32	7.5MM FLUTED ACORN	46269
RED-8	3MM FLUTED MATCHSTICK	46269
RED-9	6.4MM FLUTED DRUM	46269
SIL-0	1.12MM X 6.35MM FLUTED ROUTER	46269
SIL-1	1.85MM X 16MM FLUTED ROUTER	46269



Catalog No.	Description	GMDN
SIL-10	9.5MM FLUTED DRUM	46269
SIL-14	25.4MM DIAMOND DISC	46269
SIL-14-17	17MM DIAMOND DISC	46269
SIL-15	3.2MM FLUTED CARBIDE SIDE CUTTER	46269
SIL-1510	1.55MM X 10MM TWIST DRILL	46269
SIL-16XL2	6.7MM X 45MM CORING TOOL	46269
SIL-17-3	3MM DIAMOND BALL	46269
SIL-17-4	4MM DIAMOND BALL	46269
SIL-17-4C	4MM COARSE DIAMOND BALL	46269
SIL-17-4CX	4MM EXTRA COARSE DIAMOND BALL	46269
SIL-17-5	5MM DIAMOND BALL	46269
SIL-17-5CX	5MM EXTRA COARSE DIAMOND BALL	46269
SIL-17-6	6MM DIAMOND BALL	46269
SIL-2	2.15MM X 25.4MM FLUTED ROUTER	46269
SIL-23	14.7MM CORING TOOL	46269
SIL-24	6MM FLUTED ACORN	46269
SIL-2XL	3.05MM X 38.2MM FLUTED ROUTER	46269
SIL-3	3MM FLUTED BALL	46269
SIL-3-10	1.93MM SUT PASS DRILL/1.17 EYE	46269
SIL-32	7.5MM FLUTED ACORN	46269
SIL-38	9.2MM FLUTED ACORN	46269
SIL-39	5MM FLUTED ACORN	46269
SIL-4	4MM FLUTED BALL	46269
SIL-464-4	TWIST DRILL- 2MM X 4MM SCRW	46269
SIL-466-6	TWIST DRILL- 2MM X 6MM SCRW	46269
SIL-47	6.2MM BELL SHAPE (SIDE CUT)	46269
SIL-5	5MM FLUTED BALL	46269
SIL-6	6MM FLUTED BALL	46269
SIL-7	7MM FLUTED BALL	46269
SIL-7-9	9MM FLUTED BALL	46269
SIL-8	3MM FLUTED MATCHSTICK	46269
SIL-8-18	1.8MM FLUTED MATCHSTICK	46269
SIL-9	6.4MM FLUTED DRUM	46269
SIL-DS-A	1.7MM X 11.9MM DRILL W/DP STOP, AESCULAP®	46269
TURQ-1	1.4MM X 12.8MM FLUTED ROUTER	46269
TURQ-17-2	2MM DIAMOND BALL	46269
TURQ-17-3	3MM DIAMOND BALL	46269

Catalog No.	Description	GMDN
TURQ-17-4	4MM DIAMOND BALL	46269
TURQ-17-5C	5MM COARSE DIAMOND BALL	46269
TURQ-17-6	6MM DIAMOND BALL	46269
TURQ-3	3MM FLUTED BALL	46269
TURQ-4	4MM FLUTED BALL	46269
TURQ-406-6	TWIST DRILL-1.25MMX6MM SCRW	46269
TURQ-434-4	TWIST DRILL-1.5MMX4MM SCRW	46269
TURQ-436-6	TWIST DRILL-1.5MMX6MM SCRW	46269
TURQ-5	5MM FLUTED BALL	46269
TURQ-6	6MM FLUTED BALL	46269
TURQ-8	3MM FLUTED MATCHSTICK	46269
TURQ-L1	1.4MM X 12.8MM FLUTED ROUTER	46269
TURQ-L17-2	2MM DIAMOND BALL	46269
TURQ-L17-3	3MM DIAMOND BALL	46269
TURQ-L17-3C	3MM COARSE DIAMOND BALL	46269
TURQ-L17-4	4MM DIAMOND BALL	46269
TURQ-L17-4C	4MM COARSE DIAMOND BALL	46269
TURQ-L17-4CX	4MM EXTRA COARSE DIAMOND BALL	46269
TURQ-L17-5	5MM DIAMOND BALL	46269
TURQ-L17-5C	5MM COARSE DIAMOND BALL	46269
TURQ-L17-5CX	5MM EXTRA COARSE DIAMOND BALL	46269
TURQ-L17-6C	6MM COARSE DIAMOND BALL	46269
TURQ-L17-6CX	6MM EXTRA COARSE DIAMOND BALL	46269
TURQ-L17-7CX	7MM EXTRA COARSE DIAMOND BALL	46269
TURQ-L3	3MM FLUTED BALL	46269
TURQ-L4	4MM FLUTED BALL	46269
TURQ-L5	5MM FLUTED BALL	46269
TURQ-L6	6MM FLUTED BALL	46269
TURQ-L8	3MM FLUTED MATCHSTICK	46269
TURQ-L8-18	1.8MM FLUTED MATCHSTICK	46269
TURQ-L8-23	2.3MM FLUTED MATCHSTICK	46269
TURQ-L8D-25	2.5MM DIAMOND MATCHSTICK	46269
TURQ-L8-L	3MM FLUTED MATCHSTICK, EXTENDS 20.8MM	46269
TURQ-L8-M	3MM FLUTED MTCHSTK,LESS AGGRES	46269
TURQ-L9-58	5MM X 8.4MM FLUTED DRUM	46269
VIO-17-3	3MM DIAMOND BALL	46269
VIO-17-4	4MM DIAMOND BALL	46269

Catalog No.	Description	GMDN
VIO-17-5	5MM DIAMOND BALL	46269
VIO-17-6CX	6MM EXTRA COARSE DIAMOND BALL	46269
VIO-2	2.15MM X 25.4MM FLUTED ROUTER	46269
VIO-24	6MM FLUTED ACORN	46269
VIO-2XL	3.05MM X 38.2MM FLUTED ROUTER	46269
VIO-3	3MM FLUTED BALL	46269
VIO-32	7.5MM FLUTED ACORN	46269
VIO-38	9.2MM FLUTED ACORN	46269
VIO-4	4MM FLUTED BALL	46269
VIO-40-4	4MM X 8MM FLUTED OVAL	46269
VIO-40-5	5MM X 10MM FLUTED OVAL	46269
VIO-5	5MM FLUTED BALL	46269
VIO-6	6MM FLUTED BALL	46269
VIO-7-2	2MM FLUTED BALL	46269
VIO-8	3MM FLUTED MATCHSTICK	46269
VIO-8-18	1.8MM FLUTED MATCHSTICK	46269
VIO-87-5	5MM X 10MM FLUTED BARREL	46269
VIO-8-M	3MM FLUTED MTCHSTK-LESS AGGRES	46269

## Deklaracja zgodności

Firma Anspach Effort, Inc. (4500 Riverside Drive, Palm Beach Gardens, Floryda 33410, USA) niniejszym deklaruje na swoją wyłączną odpowiedzialność, że wyrób medyczny/rodzina wyrobów [narzędzia do dyssekcji G1 i narzędzia do dyssekcji MA] (klasa [IIa]) spełniają wszystkie wymagania:

dyrektywy Rady Europejskiej 93/42/EWG (obowiązującej).

Niniejszym deklarujemy zgodność ww. wyrobu medycznego/rodziny wyrobów z dyrektywą Rady 93/42/EWG, załącznik I, w tym ze stosownymi normami wskazanymi na liście kontrolnej zasadniczych wymogów oraz w załączniku V i VII.

Wyrób medyczny/rodzinę wyrobów (narzędzia do dyssekcji G1) po raz pierwszy opatrzono oznakowaniem CE w roku [22 listopada 2023 r.].

Załączono listę wyrobów medycznych objętych niniejszą deklaracją zgodności.

Przedstawiciel w WE:	Jednostka notyfikowana (załącznik V):
DePuy Ireland UC	BSI Group The Netherlands B.V.
Loughbeg, Ringaskiddy Co.Cork, Irlandia	Say Building John M. Keynesplein 9 1066 EP Amsterdam Niderlandy
Tel.: +353 214914278 Faks: +353 214914199	Tel.: +31 20 346 07 80
	Numer identyfikacyjny jednostki notyfikowanej 2797
	Certyfikat CE: CE 541784 Ważny do: 27 listopada 2023 r.

**Producent:**

Anspach Effort, Inc.  
4500 Riverside Drive  
Palm Beach Gardens, FL 33410  
USA

**Denise Haley**

Denise Haley  
Starsza specjalistka ds. rejestracji wyrobów

**Tamara West**

Tamara J. West  
Kierownik ds. rejestracji wyrobów

Podpisane cyfrowo przez Denise Haley  
DN: c=US, o=JW, ou=Subskrybenci, cn=Denise Haley, 09.2342.19200300.100.1.1=702275366  
Uzasadnienie: zatwierdzam niniejszy dokument  
Data: 2021.07.07 09:09:18 -04'00'  
Wersja Adobe Acrobat DC: 2015.006.30527

Data

Podpisane cyfrowo przez Tamara West  
DN: c=US, o=JW, ou=Subskrybenci, cn=Tamara West, 09.2342.19200300.100.1.1=1030416  
Uzasadnienie: zatwierdzam niniejszy dokument  
Data: 2021.07.07 11:18:34 -04'00'  
Wersja Adobe Acrobat DC: 2015.006.30527

Data

*Niniejsza deklaracja zgodności z europejską dyrektywą dotyczącą wyrobów medycznych 93/42/EWG została ponownie wydana i podpisana ze względów administracyjnych.*

*Potwierdzamy, że produkty te uwzględnione zostały w aktualnej deklaracji zgodności CE przed datą wejścia w życie (26 maja 2021 r.) rozporządzenia (UE) 2017/745 i mogą nadal być wprowadzane do*

*obrotu zgodnie z art. 120 Przepisy przejściowe rozporządzenia.*

## Declaration of Conformity

The Anspach Effort, Inc. (4500 Riverside Drive, Palm Beach Gardens, Florida 33410, USA) hereby declares under its sole responsibility that the medical device/device family [G1 Dissection Tools and MA Dissection Tools] (Class [IIa]) meets all the provisions of the:

European Council Directive 93/42/EEC (which apply).

We hereby declare the conformity of above mentioned medical device/device family according to the European Council Directive 93/42/EEC, Annex I including applicable standards as indicated in the Essential Requirements Checklist and Annex V and VII.

The G1 Dissection Tools medical device/device family was initially CE released in the year [22 November 2013].

The list of medical devices covered by this Declaration of Conformity is attached.

EC Representative:	Notified Body (Annex V):
DePuy Ireland UC  Loughbeg, Ringaskiddy Co.Cork, Ireland  Tel: +353 214914278 Fax: +353 214914199	BSI Group The Netherlands B.V.  Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands  Tel: +31 20 346 07 80  Notified Body Identification Number 2797  CE Certificate: CE 541784 Valid Until: 27 November 2023

**Manufacturer:**

The Anspach Effort, Inc.  
4500 Riverside Drive  
Palm Beach Gardens, FL 33410  
USA

**Denise Haley**

Denise Haley  
Sr. Regulatory Affairs Specialist

**Tamara West**

Tamara J. West  
Regulatory Affairs Manager

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DN: c=US, o=INJ, ou=Subscribers, cn=Denise Haley, 0.9.2342.19200300.100.1.1=702275366  
Reason: I am approving this document.  
Date: 2021.07.07 09:09:18 -0400  
Adobe Acrobat DC version: 2015.006.30527

Date

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DN: c=US, o=INJ, ou=Subscribers, cn=Tamara West, 0.9.2342.19200300.100.1.1=1030416  
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Date: 2021.07.07 11:18:34 -0400  
Adobe Acrobat DC version: 2015.006.30527

Date

*This Declaration of Conformity to European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes.*

*We confirm that these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provisions of the Regulation.*

**Product List**

<b>Catalog No.</b>	<b>Description</b>	<b>GMDN</b>
A-CRN-4-G1	1.85 mm x 16 mm Fluted Router, 4-Series.	46269
A-CRN-G1	1.85 mm x 16 mm Fluted Router.	46269
A-CRN-M-G1	2 mm x 15.6 mm Fluted Router.	46269
A-CRN-S-4-G1	2.15 mm x 22 mm Fluted Spiral Router, 4-Series.	46269
A-CRN-S-G1	2.15 mm x 22 mm Fluted Spiral Router.	46269
ADG-10-G1	1.0 mm Twist Drill for 1.25 mm Screw.	46269
ADG-11-G1	1.1 mm Twist Drill for 1.50 mm Screw.	46269
ADG-13-G1	1.3 mm Twist Drill for 1.7 mm Screw.	46269
ADG-155-G1	1.55 mm Twist Drill for 2.0 mm Screw.	46269
L-10DRC-G1	10 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-1R-G1	1.2 mm x 12.8 mm Fluted Router.	46269
L-1SB-G1	1 mm Fluted Ball, Standard Length.	46269
L-1SD-G1	1 mm Diamond Ball, Standard Length.	46269
L-2B-HX-G1	2 mm Fluted Ball, Helix, Extended Length	46269
L-2SB-G1	2 mm Fluted Ball, Standard Length.	46269
L-2SB-HX-G1	2 mm Fluted Ball, Helix, Standard Length	46269
L-2SD-G1	2 mm Diamond Ball, Standard Length.	46269
L-35DR-G1	3.5 mm x 8.4 mm Fluted Drum.	46269
L-3B-HX-G1	3 mm Fluted Ball, Helix, Extended Length	46269
L-3SB-4-G1	3 mm Fluted Ball, 4-Series, Standard Length.	46269
L-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
L-3SB-HX-G1	3mm Fluted Ball, Helix, Standard Length	46269
L-3SDC-G1	3 mm Coarse Diamond Ball, Standard Length.	46269
L-3SD-G1	3 mm Diamond Ball, Standard Length.	46269
L-47DRM-G1	4.7 mm x 8 mm Fluted Drum.	46269
L-4B-4-G1	4 mm Fluted Ball, 4-Series.	46269
L-4BA-G1	4 mm x 8 mm Fluted Barrel.	46269
L-4BA-S-G1	4 mm x 8 mm Fluted Barrel.	46269
L-4B-C-G1	4 mm Carbide Fluted Ball.	46269
L-4B-G1	4 mm Fluted Ball.	46269
L-4B-HX-G1	4 mm Fluted Ball, Helix	46269
L-4DC-G1	4 mm Coarse Diamond Ball.	46269
L-4D-G1	4 mm Diamond Ball, Standard Length.	46269
L-4DRM-G1	4 mm x 8.9 mm Fluted Drum, Side Cut Only.	46269

Catalog No.	Description	GMDN
L-4DX-G1	4 mm Extra Coarse Diamond Ball.	46269
L-4OV-G1	4 mm x 8 mm Fluted Oval.	46269
L-56OV-G1	5 mm x 6 mm Fluted Oval.	46269
L-58OV-G1	5 mm x 8 mm Fluted Oval.	46269
L-5AC-G1	5 mm Fluted Acorn.	46269
L-5B-4-G1	5 mm Fluted Ball, 4-Series.	46269
L-5BA-G1	5 mm Carbide Fluted Ball	46269
L-5B-A-G1	5 mm Fluted Ball, Less Aggressive.	46269
L-5B-C-G1	5 mm x 10 mm Fluted Barrel.	46269
L-5B-G1	5 mm Fluted Ball.	46269
L-5B-HX-G1	5 mm Fluted Ball, Helix	46269
L-5DC-G1	5 mm Coarse Diamond Ball.	46269
L-5D-G1	5 mm Diamond Ball.	46269
L-5DRC-G1	5 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-5DRM-G1	5 mm x 8.4 mm Fluted Drum.	46269
L-5DX-G1	5 mm Extra Coarse Diamond Ball.	46269
L-5OV-G1	5 mm x 10 mm Fluted Oval.	46269
L-68DRMDX-G1	6.8 mm x 10.6 mm Extra Coarse Diamond Drum.	46269
L-6B-4-G1	6 mm Fluted Ball, 4-Series.	46269
L-6B-G1	6 mm Fluted Ball.	46269
L-6B-HX-G1	6 mm Fluted Ball, Helix	46269
L-6DC-G1	6 mm Coarse Diamond Ball. .	46269
L-6D-G1	6 mm Diamond Ball.	46269
L-6DRC-G1	6 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-6DX-20-G1	6 mm Extra Coarse Diamond Ball, 20/30 Grit.	46269
L-6DX-G1	6 mm Extra Coarse Diamond Ball.	46269
L-7AC-G1	7 mm Fluted Acorn.	46269
L-7B-G1	7 mm Fluted Ball.	46269
L-7B-HX-G1	7 mm Fluted Ball, Helix	46269
L-7DRC-11-G1	7 mm x 11 mm Fluted Drum.	46269
L-7DRC-G1	7 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-8BA-G1	8 mm x 12.5 mm Fluted Barrel.	46269
L-8DRC-11-G1	8 mm x 11 mm Fluted Drum.	46269
L-8DRC-G1	8 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-8DX-G1	8 mm Extra Coarse Diamond Ball.	46269
L-8N-18-G1	1.8 mm Fluted Matchstick.	46269
L-8ND-G1	2.5 mm Diamond Matchstick.	46269



Catalog No.	Description	GMDN
L-8N-G1	2.3 mm Fluted Matchstick.	46269
L-8NSDC-G1	3.2 mm Coarse Diamond Matchstick.	46269
L-8NSD-G1	3.2 mm Diamond Matchstick.	46269
L-8NS-G1	3 mm Fluted Matchstick.	46269
L-8NS-M-C-G1	3 mm Carbide Fluted Matchstick, Less Aggressive.	46269
L-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
L-9B-G1	9 mm Fluted Ball.	46269
L-9DRC-G1	9 mm x 14 mm Fluted Drum, Side Cut Only.	46269
L-CRN-G1	2.5 mm x 25.4 mm Fluted Router.	46269
L-CRN-S-4-G1	2.47 mm x 30.3 mm Fluted Spiral Router, 4-Series.	46269
L-CRN-S-G1	2.47 mm x 30.3 mm Fluted Spiral Router.	46269
LHD-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
LHD-47-5-G1	3.2 mm Fluted Bell.	46269
LHD-4B-G1	4 mm Fluted Ball.	46269
LHD-5B-G1	5 mm Fluted Ball.	46269
LHD-5DRM12-G1	5 mm x 12 mm Fluted Drum.	46269
LHD-5DRM-G1	5 mm x 8.4 mm Fluted Drum.	46269
LHD-5DRM-L-G1	5 mm x 16.2 mm Fluted Drum.	46269
LHD-64DRM-G1	6.4 mm Fluted Drum.	46269
LHD-6AC-G1	6 mm Fluted Acorn.	46269
LHD-6B-G1	6 mm Fluted Ball.	46269
LHD-7B-G1	7 mm Fluted Ball.	46269
LHD-8NS-G1	3 mm Fluted Matchstick.	46269
LHD-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
LHD-95DRM-G1	9.5 mm Fluted Drum.	46269
LHD-LS9-35-G1	3.5 mm x 19.8 mm Fluted Drum.	46269
LHD-LS9-5-G1	4.7 mm x 20 mm Fluted Drum.	46269
LHD-LS9-76-G1	7.6 mm x 28.6 mm Fluted Drum.	46269
M-05D-G1	0.5 mm Diamond Ball, Extended Length.	46269
M-05SD-G1	0.5 mm Diamond Ball, Standard Length.	46269
M-14R-G1	1.4 mm x 12.8 mm Fluted Router.	46269
M-15D-G1	1.5 mm Diamond Ball, Extended Length.	46269
M-15SDC-G1	1.5 mm Coarse Diamond Ball, Standard Length.	46269
M-15SD-G1	1.5 mm Diamond Ball, Standard Length.	46269
M-1B-G1	1 mm Fluted Ball, Extended Length.	46269
M-1DC-G1	1 mm Coarse Diamond Ball, Extended Length.	46269
M-1D-G1	1 mm Diamond Ball, Extended Length.	46269

Catalog No.	Description	GMDN
M-1R-4-G1	1.2 mm x 12.8 mm Fluted Router, 4-Series.	46269
M-1R-G1	1.2 mm x 12.8 mm Fluted Router.	46269
M-1SB-G1	1 mm Fluted Ball, Standard Length.	46269
M-1SDC-G1	1 mm Coarse Diamond Ball, Standard Length.	46269
M-1SD-G1	1 mm Diamond Ball, Standard Length.	46269
M-25SDC-G1	2.5 mm Coarse Diamond Ball, Standard Length.	46269
M-25SD-G1	2.5 mm Diamond Ball, Standard Length.	46269
M-2B-G1	2 mm Fluted Ball, Extended Length.	46269
M-2B-HX-G1	2 mm Fluted Ball, Helix, Extended Length	46269
M-2DC-G1	2 mm Coarse Diamond Ball, Extended Length.	46269
M-2D-G1	2 mm Diamond Ball, Extended Length.	46269
M-2SB-G1	2 mm Fluted Ball, Standard Length.	46269
M-2SB-HX-G1	2 mm Fluted Ball, Helix, Standard Length	46269
M-2SDC-G1	2 mm Coarse Diamond Ball, Standard Length.	46269
M-2SD-G1	2 mm Diamond Ball, Standard Length.	46269
M-35SDC-G1	3.5 mm Coarse Diamond Ball, Standard Length.	46269
M-35SD-G1	3.5 mm Diamond Ball, Standard Length.	46269
M-3BA-A-G1	3 mm x 11.3 mm Fluted Barrel, 14 Flutes.	46269
M-3B-G1	3 mm Fluted Ball, Extended Length.	46269
M-3B-HX-G1	3 mm Fluted Ball, Helix, Extended Length	46269
M-3DC-2-G1	3 mm Coarse Diamond Ball.	46269
M-3DC-G1	3 mm Coarse Diamond Ball, Extended Length.	46269
M-3D-G1	3 mm Diamond Ball, Extended Length.	46269
M-3SB-2-G1	3 mm Fluted Ball.	46269
M-3SB-4-G1	3 mm Fluted Ball, 4-Series, Standard Length.	46269
M-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
M-3SB-HX-G1	3 mm Fluted Ball, Helix, Standard Length	46269
M-3SDC-G1	3 mm Coarse Diamond Ball, Standard Length.	46269
M-3SD-G1	3 mm Diamond Ball, Standard Length.	46269
M-45DRMDX-G1	4 mm x 5 mm Extra Coarse Diamond Drum.	46269
M-4AC-G1	4 mm Fluted Acorn.	46269
M-4B-27-G1	4 mm Fluted Ball.	46269
M-4B-4-G1	4 mm Fluted Ball, 4-Series.	46269
M-4BA-A-G1	4 mm x 11 mm Fluted Barrel, 14 Flutes.	46269
M-4B-G1	4 mm Fluted Ball.	46269
M-4B-HX-G1	4 mm Fluted Ball, Helix	46269
M-4DC-G1	4 mm Coarse Diamond Ball.	46269

Catalog No.	Description	GMDN
M-4D-G1	4 mm Diamond Ball.	46269
M-4DRM-G1	4 mm x 8.9 mm Fluted Drum, Side Cut Only.	46269
M-4DX-20-G1	4 mm Extra Coarse Diamond Ball, 20/30 Grit.	46269
M-4DX-G1	4 mm Extra Coarse Diamond Ball.	46269
M-4FD-G1	4 mm x 10 mm Diamond Pear Inverted.	46269
M-4OVDC-G1	4 mm x 8 mm Coarse Diamond Oval.	46269
M-4OVD-G1	4 mm x 8 mm Diamond Oval.	46269
M-4OV-G1	4 mm x 8 mm Fluted Oval.	46269
M-55OV-C-G1	5.5 mm x 10 mm Carbide Fluted Oval.	46269
M-56OV-G1	5 mm x 6 mm Fluted Oval.	46269
M-58OV-G1	5 mm x 8 mm Fluted Oval.	46269
M-5AC-G1	5 mm Fluted Acorn.	46269
M-5B-12F-G1	5 mm Fluted Ball, 12 Flutes.	46269
M-5B-27-G1	5 mm Fluted Ball.	46269
M-5B-2-G1	5 mm Fluted Ball.	46269
M-5B-4-G1	5 mm Fluted Ball, 4-Series.	46269
M-5BA-20-G1	5 mm x 20 mm Fluted Barrel.	46269
M-5BA-A-G1	5 mm x 11.3 mm Fluted Barrel.	46269
M-5B-A-G1	5 mm Fluted Ball, Less Aggressive.	46269
M-5B-C-G1	5 mm Carbide Fluted Ball.	46269
M-5B-G1	5 mm Fluted Ball.	46269
M-5B-HX-G1	5 mm Fluted Ball, Helix	46269
M-5DC-G1	5 mm Coarse Diamond Ball.	46269
M-5D-G1	5 mm Diamond Ball.	46269
M-5DRM-G1	5 mm x 8.4 mm Fluted Drum. .	46269
M-5DX-G1	5 mm Extra Coarse Diamond Ball	46269
M-5OV-G1	5 mm x 10 mm Fluted Oval.	46269
M-62DRM-G1	6.2 mm x 4.6 mm Fluted Drum, Side Cut Only.	46269
M-6AC-G1	6 mm Fluted Acorn.	46269
M-6B-4-G1	6 mm Fluted Ball, 4-Series.	46269
M-6BA-A-G1	6 mm x 11.3 mm Fluted Barrel.	46269
M-6B-C-G1	6 mm Carbide Fluted Ball.	46269
M-6B-G1	6 mm Fluted Ball.	46269
M-6B-HX-G1	6 mm Fluted Ball, Helix	46269
M-6DC-2-G1	6 mm Coarse Diamond Ball.	46269
M-6DC-G1	6 mm Coarse Diamond Ball.	46269
M-6D-G1	6 mm Diamond Ball.	46269

Catalog No.	Description	GMDN
M-6DX-20-G1	6 mm Extra Coarse Diamond Ball, 20/30 Grit.	46269
M-6DX-G1	6 mm Extra Coarse Diamond Ball.	46269
M-6P-G1	6 mm x 9 mm Fluted Pear.	46269
M-7AC-G1	7 mm Fluted Acorn.	46269
M-7B-G1	7 mm Fluted Ball.	46269
M-7B-HX-G1	7 mm Fluted Ball, Helix	46269
M-7DX-G1	7 mm Extra Coarse Diamond Ball.	46269
M-8BA-G1	8 mm x 12.5 mm Fluted Barrel.	46269
M-8N-18-G1	1.8 mm Fluted Matchstick	46269
M-8ND-G1	2.5 mm Diamond Matchstick.	46269
M-8N-G1	2.3 mm Fluted Matchstick.	46269
M-8NSDC-G1	3.2 mm Coarse Diamond Matchstick.	46269
M-8NSD-G1	3.2 mm Diamond Matchstick.	46269
M-8NS-G1	3 mm Fluted Matchstick.	46269
M-8NS-M-C-G1	3 mm Carbide Fluted Matchstick, Less Aggressive.	46269
M-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
M-8NS-ML-G1	3.2 mm Fluted Matchstick, Less Aggressive.	46269
MHD-126BT-G1	12.6 mm x 10.4 mm Boring Tool, 3 Flutes.	46269
MHD-15C-G1	3.2 mm Fluted Carbide Side Cutter.	46269
MHD-16CT-G1	6.7 mm Coring Tool.	46269
MHD-17DD-G1	17 mm Diamond Disc.	46269
MHD-19CT-G1	9.9 mm Coring Tool.	46269
MHD-25DD-G1	25.4 mm Diamond Disc.	46269
MHD-25R-G1	2.15 mm x 25.4 mm Fluted Router.	46269
MHD-3DRMC-G1	3 mm x 9.5 mm Fluted Carbide Drum.	46269
MHD-62DRM-G1	6.2 mm x 4.6 mm Fluted Drum, Side Cut Only.	46269
MHD-6AC-G1	6 mm Fluted Acorn.	46269
MHD-6B-G1	6 mm Fluted Ball.	46269
MHD-8NS-G1	3 mm Fluted Matchstick.	46269
MHD-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
MHD-95DRM-G1	9.5 mm Fluted Drum.	46269
MHD-97B-G1	12.6 mm Boring Tool.	46269
MHD-98B-G1	9.5 mm Boring Tool.	46269
MHD-9B-G1	9 mm Fluted Ball.	46269
MIA16-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
MIA16-4B-G1	4 mm Fluted Ball.	46269
MIA16-4DC-G1	4 mm Coarse Diamond Ball.	46269

Catalog No.	Description	GMDN
MIA16-4D-G1	4 mm Diamond Ball.	46269
MIA16-5D-G1	5 mm Diamond Ball.	46269
MIA16-5OV-G1	5 mm X 10 mm Fluted Oval.	46269
MIA16-6B-G1	6 mm Fluted Ball.	46269
MIA16-6DC-G1	6 mm Coarse Diamond Ball.	46269
MIA16-6DX-G1	6 mm Extra Coarse Diamond Ball.	46269
MIA16-7B-G1	7 mm Fluted Ball.	46269
MIA16-8NS-G1	3 mm Fluted Matchstick.	46269
MIA16-8NSM-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
P-CRN-4-G1	1.4 mm x 12.8 mm Fluted Router, 4-Series.	46269
P-CRN-G1	1.4 mm x 12.8 mm Fluted Router.	46269
P-CRN-M-G1	1.3 mm x 12.8 mm Fluted Router.	46269
S-05B-G1	0.5 mm Fluted Ball, Extended Length.	46269
S-05D-G1	0.5 mm Diamond Ball, Extended Length.	46269
S-05SD-G1	0.5 mm Diamond Ball, Standard Length.	46269
S-06SD-G1	0.6 mm Diamond Ball, Standard Length.	46269
S-08SD-G1	0.8 mm Diamond Ball, Standard Length.	46269
S-1203TD-G1	1.2 mm x 3 mm Twist Drill.	46269
S-1254TD-G1	Twist Drill for 1.25 mm x 4 mm Screw.	46269
S-12D-G1	1.2 mm Diamond Ball, Extended Length.	46269
S-1504TD-G1	Twist Drill for 1.5 mm x 4 mm Screw.	46269
S-1506TD-G1	Twist Drill for 1.5 mm x 6 mm Screw.	46269
S-1506TD-M-G1	1.5 mm x 6 mm Fluted Twist Drill.	46269
S-1510TD-G1	1.55 mm x 10 mm Fluted Twist Drill.	46269
S-15B-G1	1.5 mm Fluted Ball, Extended Length.	46269
S-15DC-G1	1.5 mm Coarse Diamond Ball, Extended Length.	46269
S-15DCT-G1	1.5 mm Coarse Diamond Ball, Tapered, Extended	46269
S-15D-G1	1.5 mm Diamond Ball, Extended Length.	46269
S-15DRMC-G1	1.5 mm x 7.5 mm Cylindrical Carbide Drum.	46269
S-15DRMC-L-G1	1.5 mm x 7.5 mm Cylindrical Carbide Drum.	46269
S-15SB-G1	1.5 mm Fluted Ball, Standard Length.	46269
S-15SDC-G1	1.5 mm Coarse Diamond Ball, Standard Length.	46269
S-15SD-G1	1.5 mm Diamond Ball, Standard Length.	46269
S-1B-C-G1	1 mm Carbide Fluted Ball, Extended Length.	46269
S-1B-G1	1 mm Fluted Ball, Extended Length.	46269
S-1DC-G1	1 mm Coarse Diamond Ball, Extended Length.	46269
S-1D-G1	1 mm Diamond Ball, Extended Length.	46269

Catalog No.	Description	GMDN
S-1R-4-G1	1.4 mm x 12.8 mm Fluted Router, 4-Series.	46269
S-1R-G1	1.4 mm x 12.8 mm Fluted Router.	46269
S-1SB-C-G1	1 mm Carbide Fluted Ball, Standard Length.	46269
S-1SB-G1	1 mm Fluted Ball, Standard Length.	46269
S-1SDC-G1	1 mm Coarse Diamond Ball, Standard Length.	46269
S-1SD-G1	1 mm Diamond Ball, Standard Length.	46269
S-2004TD-G1	Twist Drill for 2.0 mm x 4 mm Screw.	46269
S-2006TD-G1	Twist Drill for 2.0 mm x 6 mm Screw.	46269
S-2433TD-G1	2.4 mm x 3.3 mm Twist Drill.	46269
S-25B-G1	2.5 mm Fluted Ball, Extended Length.	46269
S-25B-HX-G1	2.5 mm Fluted Ball, Helix, Extended Length	46269
S-25DC-G1	2.5 mm Coarse Diamond Ball, Extended Length.	46269
S-25D-G1	2.5 mm Diamond Ball, Extended Length.	46269
S-25SB-G1	2.5 mm Fluted Ball, Standard Length.	46269
S-25SB-HX-G1	2.5 mm Fluted Ball, Helix, Standard Length	46269
S-25SDC-G1	2.5 mm Coarse Diamond Ball, Standard Length.	46269
S-25SD-G1	2.5 mm Diamond Ball, Standard Length.	46269
S-2B-C-G1	2 mm Carbide Fluted Ball, Extended Length.	46269
S-2B-G1	2 mm Fluted Ball, Extended Length.	46269
S-2B-HX-G1	2 mm Fluted Ball, Helix, Extended Length	46269
S-2DC-G1	2 mm Coarse Diamond Ball, Extended Length.	46269
S-2D-G1	2 mm Diamond Ball, Extended Length.	46269
S-2SB-4-G1	2 mm Fluted Ball, 4-Series, Standard Length.	46269
S-2SB-C-8F-G1	2 mm Carbide Fluted Ball, Standard, 8 Flutes.	46269
S-2SB-C-G1	2 mm Carbide Fluted Ball, Standard Length.	46269
S-2SB-G1	2 mm Fluted Ball, Standard Length.	46269
S-2SB-HX-G1	2 mm Fluted Ball, Helix, Standard Length	46269
S-2SBT-G1	2 mm Fluted Ball, Tapered, Standard Length.	46269
S-2SD-120-G1	2 mm Diamond Ball, 120/140 Grit, Standard Length.	46269
S-2SDC-G1	2 mm Coarse Diamond Ball, Standard Length.	46269
S-2SDCT-G1	2 mm Coarse Diamond Ball, Tapered, Standard Length.	46269
S-2SD-G1	2 mm Diamond Ball, Standard Length.	46269
S-35B-G1	3.5 mm Fluted Ball, Extended Length.	46269
S-35B-HX-G1	3.5 mm Fluted Ball, Helix, Extended Length	46269
S-35DC-G1	3.5 mm Coarse Diamond Ball, Extended Length.	46269
S-35D-G1	3.5 mm Diamond Ball, Extended Length.	46269
S-35SB-G1	3.5 mm Fluted Ball, Standard Length.	46269



Catalog No.	Description	GMDN
S-35SB-HX-G1	3.5 mm Fluted Ball, Helix, Standard Length	46269
S-35SDC-G1	3.5 mm Coarse Diamond Ball, Standard Length.	46269
S-35SD-G1	3.5 mm Diamond Ball, Standard Length.	46269
S-3B-4-G1	3 mm Fluted Ball, 4-Series, Extended Length.	46269
S-3B-C-G1	3 mm Carbide Fluted Ball, Extended Length.	46269
S-3B-G1	3 mm Fluted Ball, Extended Length.	46269
S-3B-HX-G1	3 mm Fluted Ball, Helix, Extended Length	46269
S-3DC-G1	3 mm Coarse Diamond Ball, Extended Length.	46269
S-3D-G1	3 mm Diamond Ball, Extended Length.	46269
S-3SB-4-G1	3 mm Fluted Ball, 4-Series, Standard Length.	46269
S-3SB-C-G1	3 mm Carbide Fluted Ball, Standard Length.	46269
S-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
S-3SB-HX-G1	3 mm Fluted Ball, Helix, Standard Length	46269
S-3SBT-G1	3 mm Fluted Ball, Tapered, Standard Length.	46269
S-3SD-100-G1	3 mm Diamond Ball, 100/120 Grit, Standard Length.	46269
S-3SDC-22-G1	3 mm Coarse Diamond Ball.	46269
S-3SDC-50-G1	3 mm Coarse Diamond Ball, 50/60 Grit, Standard Length.	46269
S-3SDC-G1	3 mm Coarse Diamond Ball, Standard Length.	46269
S-3SDCT-G1	3 mm Coarse Diamond Ball, Tapered, Standard Length.	46269
S-3SD-G1	3 mm Diamond Ball, Standard Length.	46269
S-4B-4-G1	4 mm Fluted Ball, 4-Series.	46269
S-4B-C-10F-G1	4 mm Carbide Fluted Ball, 10 Flutes.	46269
S-4B-C-G1	4 mm Carbide Fluted Ball, Standard Length.	46269
S-4B-G1	4 mm Fluted Ball.	46269
S-4B-HX-G1	4 mm Fluted Ball, Helix	46269
S-4BL-C-G1	4 mm Carbide Fluted Ball.	46269
S-4BT-G1	4 mm Fluted Ball, Tapered.	46269
S-4D-100-G1	4 mm Diamond Ball, 100/120 Grit.	46269
S-4DC-22-G1	4 mm Coarse Diamond Ball.	46269
S-4DC-G1	4 mm Coarse Diamond Ball.	46269
S-4D-G1	4 mm Diamond Ball.	46269
S-4D-L-G1	4 mm Diamond Ball.	46269
S-4DRM-G1	4 mm x 8.9 mm Fluted Drum, Side Cut Only.	46269
S-4DX-20-G1	4 mm Coarse Diamond Ball, 20/30 Grit.	46269
S-4DX-G1	4 mm Extra Coarse Diamond Ball.	46269
S-4OVD-G1	4 mm x 8 mm Diamond Oval.	46269
S-4OV-G1	4 mm x 8 mm Fluted Oval.	46269

Catalog No.	Description	GMDN
S-5AC-G1	5 mm Fluted Acorn.	46269
S-5B-12F-G1	5 mm Fluted Ball, 12 Flutes.	46269
S-5B-2-G1	5 mm Fluted Ball.	46269
S-5B-4-G1	5 mm Fluted Ball, 4-Series.	46269
S-5BA-G1	5 mm x 10 mm Fluted Barrel.	46269
S-5B-C-10F-G1	5 mm Carbide Fluted Ball, 10 Flutes.	46269
S-5B-C-G1	5 mm Carbide Fluted Ball, Standard Length.	46269
S-5B-G1	5 mm Fluted Ball.	46269
S-5B-HX-G1	5 mm Fluted Ball, Helix	46269
S-5D-100-G1	5 mm Diamond Ball, 100/120 Grit.	46269
S-5D-2-G1	5 mm Diamond Ball.	46269
S-5DC-22-G1	5 mm Coarse Diamond Ball.	46269
S-5DC-40-G1	5 mm Coarse Diamond Ball, 40/60 Grit.	46269
S-5DC-G1	5 mm Coarse Diamond Ball.	46269
S-5D-G1	5 mm Diamond Ball.	46269
S-5DX-G1	5 mm Extra Coarse Diamond Ball.	46269
S-5OV-G1	5 mm x 10 mm Fluted Oval.	46269
S-62BE-G1	6.2 mm Fluted Bell, Side Cut Only.	46269
S-68DRMDC-G1	6.8 mmx 10.6 mm Coarse Diamond Drum.	46269
S-68DRMDX-G1	6.8 mmx 10.6 mm Extra Coarse Diamond Drum.	46269
S-6AC-G1	6 mm Fluted Acorn.	46269
S-6B-4-G1	6 mm Fluted Ball, 4-Series.	46269
S-6B-C-G1	6 mm Carbide Fluted Ball, Standard Length.	46269
S-6B-G1	6 mm Fluted Ball.	46269
S-6B-HX-G1	6 mm Fluted Ball, Helix	46269
S-6D-100-G1	6 mm Diamond Ball, 100/120 Grit.	46269
S-6DC-G1	6 mm Coarse Diamond Ball.	46269
S-6D-G1	6 mm Diamond Ball.	46269
S-6DX-20-G1	6 mm Coarse Diamond Ball, 20/30 Grit.	46269
S-6DX-G1	6 mm Extra Coarse Diamond Ball.	46269
S-6IP-G1	6 mm x 11.8 mm Fluted Pear, Inverted.	46269
S-6PD-G1	6 mm x 9 mm Diamond Pear.	46269
S-6P-G1	6 mm x 9 mm Fluted Pear.	46269
S-6R-G1	1.12 mm x 6.35 mm Fluted Router.	46269
S-7B-C-14F-G1	7 mm Carbide Fluted Ball, 14 Flutes.	46269
S-7B-C-G1	7 mm Carbide Fluted Ball, Standard Length.	46269
S-7B-G1	7 mm Fluted Ball.	46269



Catalog No.	Description	GMDN
S-7B-HX-G1	7 mm Fluted Ball, Helix	46269
S-7IP-G1	7 mm x 13.1 mm Fluted Pear, Inverted.	46269
S-8B-G1	8 mm Fluted Ball.	46269
S-8DC-G1	8 mm Coarse Diamond Ball.	46269
S-8N-18-4-G1	1.8 mm Fluted Matchstick, 4- Series.	46269
S-8N-18-G1	1.8 mm Fluted Matchstick.	46269
S-8ND-G1	2.5 mm Diamond Matchstick.	46269
S-8N-G1	2.3 mm Fluted Matchstick.	46269
S-8N-L-G1	2.3 mm Fluted Matchstick.	46269
S-8NSD-G1	3.2 mm Diamond Matchstick.	46269
S-8NS-G1	3 mm Fluted Matchstick.	46269
S-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
S-9AC-G1	9.2 mm Fluted Acorn.	46269
S-9B-G1	9 mm Fluted Ball.	46269
SHD-1504TD-G1	1.15 mm Twist Drill for 1.5 mm x 4 mm Screw.	46269
SHD-17DD-G1	17 mm Diamond Disc.	46269
SHD-25DD-G1	25.4 mm Diamond Disc.	46269
SHD-25R-G1	2.15 mm x 25.4 mm Fluted Router.	46269
SHD-3-10-G1	1.93 mm Suture Pass Drill / 1.17 eye.	46269
SHD-5B-G1	5 mm Fluted Ball.	46269
SHD-6AC-G1	6 mm Fluted Acorn.	46269
SHD-6B-G1	6 mm Fluted Ball.	46269
SHD-6DX-G1	6 mm Extra Coarse Diamond Ball.	46269
SHD-6R-G1	1.12 mm x 6.35 mm Fluted Router.	46269
SHD-75AC-A-G1	7.5 mm Fluted Acorn, Less Aggressive.	46269
SHD-75AC-G1	7.5 mm Fluted Acorn.	46269
SHD-7B-G1	7 mm Fluted Ball.	46269
SHD-8NS-G1	3 mm Fluted Matchstick.	46269
SHD-9AC-G1	9.2 mm Fluted Acorn.	46269
SHD-DS-A-G1	1.7 mm x 11.9 mm Twist Drill with Depth Stop, maAesculap®, max. 60,000 RPM.	46269
XLHD-25R-G1	2.15 mm x 25.4 mm Fluted Router.	46269
XLHD-3SB-G1	3 mm Fluted Ball, Standard Length.	46269
XLHD-4B-G1	4 mm Fluted Ball.	46269
XLHD-51C-G1	6.4 mm Cylindrical Carbide.	46269
XLHD-55DC-G1	5.5 mm Coarse Diamond Ball.	46269
XLHD-5B-G1	5 mm Fluted Ball.	46269

Catalog No.	Description	GMDN
XLHD-6AC-G1	6 mm Fluted Acorn.	46269
XLHD-6B-G1	6 mm Fluted Ball.	46269
XLHD-75AC-G1	7.5 mm Fluted Acorn.	46269
XLHD-7B-G1	7 mm Fluted Ball.	46269
XLHD-8NS-G1	3 mm Fluted Matchstick.	46269
XLHD-8NS-M-G1	3 mm Fluted Matchstick, Less Aggressive.	46269
XLHD-95DRM-G1	9.5 mm Fluted Drum.	46269
XLHD-9B-G1	9 mm Fluted Ball.	46269

# Certyfikat WE – Zapewnianie jakości produkcji

Dyrektywa 93/42/EWG dotycząca wyrobów medycznych, załącznik V

Nr **CE 541784**  
Wydano dla: **Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Floryda**  
**33410**  
**USA**

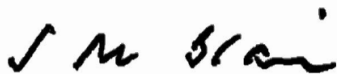
W odniesieniu do:

**Produkcja pneumatycznych i elektrycznych wiertarek chirurgicznych o wysokiej prędkości obrotowej, nasadek do końcówek, sterylnych frezarek tnących i akcesoriów.**

**Te aspekty załącznika V dotyczące osiągania i utrzymywania sterylności akcesoriów związanych z powyższymi produktami.**

w oparciu o nasze badania systemu zapewnienia jakości zgodnie z wymaganiami dyrektywy Rady 93/42/EWG, załącznik V. System zapewnienia jakości spełnia wymagania w/w dyrektywy. Wprowadzenie do obrotu wyrobów klasy IIb i klasy III wymaga uzyskania certyfikatu, o którym mowa w załączniku III.

W imieniu i na rzecz BSI, jednostki notyfikowanej do celów w/w dyrektywy (numer jednostki notyfikowanej: 0086):



Stewart Brain, Kierownik Działu ds.  
Zgodności z Przepisami i Ryzyka –  
Wyroby Medyczne

Data: **2018-12-03**

Data ważności: **2023-11-27**

Pierwsze wydanie: **2008-11-28**

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Strona 1z 2

Ważność niniejszego certyfikatu jest warunkowana utrzymywaniem systemu jakości zgodnie z wymaganiami dyrektywy, co musi zostać potwierdzone przez odpowiednie działania nadzorcze jednostki notyfikowanej. Niniejszy certyfikat nie obejmuje jakichkolwiek wyrobów zaprojektowanych lub wyprodukowanych przez osobę trzecią na rzecz firmy wskazanej w niniejszym certyfikacie, chyba że wyraźnie uzgodniono to z firmą BSI. Niniejszy certyfikat został wydany elektronicznie i jest objęty warunkami umowy.

Informacje i dane kontaktowe: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel. +44 345 080 9000  
Firma BSI Assurance UK Limited, zarejestrowana w Anglii pod numerem 7805321. Adres siedziby: 389 Chiswick High Road, Londyn W4 4AL, Wielka Brytania.  
Spółka zrzeszona w Grupie BSI.

# Certyfikat WE - Zapewnienie jakości produkcji

Informacje uzupełniające do certyfikatu nr CE 541784

Wydano dla:

**Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Floryda**  
**33410**  
**USA**

Numer	Nazwa wyrobu	Przeznaczenie zgodnie z instrukcją użytkowania
<b>Klasa IIa</b>		
MD 1104	Instrumenty pneumatyczne i elektryczne	-
MD 0106	Narzędzia do przecinania, piły, systemy nawadniania/ssania i związany z nimi osprzęt	-

Pierwsze wydanie: **2008-11-28**

Data: **2018-12-03**

Data ważności: **2023-11-27**

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Strona 2 z 2

Ważność niniejszego certyfikatu jest uwarunkowana posiadaniem systemu jakości zgodnego z wymaganiami w/w dyrektywy, co musi zostać potwierdzone przez odpowiednie działania audytowe jednostki notyfikowanej. Niniejszy certyfikat nie obejmuje jakichkolwiek wyrobów zaprojektowanych lub wyprodukowanych przez osobę trzecią na rzecz firmy wskazanej w niniejszym certyfikacie, chyba że wyraźnie uzgodniono to z firmą BSI. Niniejszy certyfikat został wydany elektronicznie i jest objęty warunkami umowy.

Informacje i dane kontaktowe: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel. +44 345 080 9000. Firma BSI Assurance UK Limited, zarejestrowana w Anglii pod numerem 7805321. Adres siedziby: 389 Chiswick High Road, Londyn W4 4AL, Wielka Brytania. Spółka zrzeszona w Grupie BSI.

# Certyfikat WE - Zapewnienie jakości produkcji

Dyrektywa 93/42/EWG dotycząca wyrobów medycznych, załącznik V

## Wykaz istotnych podwykonawców

świadczących usługi w odniesieniu do produktu, którego dotyczy:

Certyfikat nr: **CE 541784**  
Data: **2018-12-03**  
Wydano dla: **Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Floryda**  
**33410**  
**USA**

Podwykonawca:	Świadczone usługi
Millstone Medical Outsourcing LLC 580 Commerce Drive Fall River Massachusetts 02720-4759 USA	Montaż i demontaż Opakowanie
Sotera Health LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	Sterylizacja promieniami gamma
Synthes GmbH Eimattstrasse 3 Oberdorf 4436	Przedstawicielstwo w UE

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# Certyfikat WE - Zapewnienie jakości produkcji

## Historia świadectwa

Certyfikat nr: **CE 541784**  
 Data: **2018-12-03**  
 Wydano dla: **Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Floryda**  
**33410**  
**USA**

Data	Numer referencyjny	Działanie
28 listopada 2008 r.	7276988	Pierwsze wydanie na podstawie przeniesienia z innej jednostki notyfikowanej
23 października 2013 r.	8025534	Przedłużenie ważności certyfikatu. Dodanie przedstawicieli UE do listy podwykonawców, Wielkiej Brytanii dla starszych produktów i Szwajcarii dla linii nowych produktów. Dodanie podwykonawcy sterylnych opakowań, Millstone Medical Outsourcing LLC.
5 lipca 2014 r.	8180860	Rozszerzenie do zakresu obejmującego akcesoria klasy 1
17 grudnia 2014 r.	8268134	Ponowne wydanie celem dodania „montażu” oraz „opakowania” (sterylnego produktu) do podwykonawcy Millstone Medical Outsourcing
23 stycznia 2016 r.	8466597	Ponowne wydanie certyfikatu. Drobne zmiany w adresie podwykonawcy sterylizacji, Sterigenics
26 września 2016 r.	8603439	Usunięcie Anspach Europe Ltd jako przedstawiciela UE
Aktualnie	8941760	Odnowienie. Dodano matrycę z listą produktów. Zmiana podwykonawcy z Sterigenics na Sotera Health LLC.

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Strona 1 z 1

Ważność niniejszego certyfikatu jest uwarunkowana posiadaniem systemu jakości zgodnego z wymaganiami w/w dyrektywy, co musi zostać potwierdzone przez odpowiednie działania audytowe jednostki notyfikowanej. Niniejszy certyfikat nie obejmuje jakichkolwiek wyrobów zaprojektowanych lub wyprodukowanych przez osobę trzecią na rzecz firmy wskazanej w niniejszym certyfikacie, chyba że wyraźnie uzgodniono to z firmą BSI. Niniejszy certyfikat został wydany elektronicznie i jest objęty warunkami umowy.

Informacje i dane kontaktowe: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel. +44 345 080 9000  
 Firma BSI Assurance UK Limited, zarejestrowana w Anglii pod numerem 7805321. Adres siedziby: 389 Chiswick High Road, Londyn W4 4AL, Wielka Brytania.  
 Członek grupy spółek BSI.



# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.****CE 541784****Issued To:**

**The Anspach Effort, Inc.  
4500 Riverside Drive  
Palm Beach Gardens  
Florida  
33410  
USA**

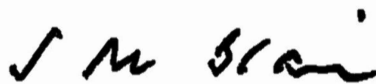
**In respect of:**

**The manufacture of high speed pneumatic and electric surgical drills, nosepiece attachments, sterile cutting burrs and accessories.**

**Those aspects of Annex V relating to achieving and maintaining sterility of accessories related to the above products.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

**First Issued: 2008-11-28****Date: 2018-12-03****Expiry Date: 2023-11-27**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Production Quality Assurance

## Supplementary Information to CE 541784

Issued To:

**The Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Florida**  
**33410**  
**USA**

Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1104	Pneumatic and Electric Powered Instruments	-
MD 0106	Dissection Tools, Saw Blades, Irrigation/Suction Systems and associated attachments	-

First Issued: **2008-11-28**Date: **2018-12-03**Expiry Date: **2023-11-27**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 541784**  
 Date: **2018-12-03**  
 Issued To: **The Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Florida**  
**33410**  
**USA**

### Subcontractor:

### Service(s) supplied

Millstone Medical Outsourcing LLC  
 580 Commerce Drive  
 Fall River  
 Massachusetts  
 02720-4759  
 USA

**Assembly  
Packaging**

Sotera Health LLC  
 305 Enterprise Drive  
 Lewis Center  
 Ohio  
 43035-9418  
 USA

**Gamma Sterilization**

Synthes GmbH  
 Eimattstrasse 3  
 Oberdorf  
 4436  
 Switzerland

**EU Representative**

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# EC Certificate - Production Quality Assurance

## Certificate History

Certificate No: **CE 541784**  
 Date: **2018-12-03**  
 Issued To: **The Anspach Effort, Inc.**  
**4500 Riverside Drive**  
**Palm Beach Gardens**  
**Florida**  
**33410**  
**USA**

Date	Reference Number	Action
28 November 2008	7276988	First issue based on transfer from another Notified Body
23 October 2013	8025534	Certificate renewal. Addition of EU Representatives to list of subcontractors, UK for legacy products and Switzerland for new product lines. Addition of sterile packaging subcontractor, Millstone Medical Outsourcing LLC.
05 July 2014	8180860	Extension to scope to include class 1 accessories
17 December 2014	8268134	Reissue for the addition of "assembly" as well as "packaging" (of sterile product) to subcontractor Millstone Medical Outsourcing LLC.
23 January 2016	8466597	Certificate reissue. Minor change to address of sterilisation subcontractor, Sterigenics
26 September 2016	8603439	Removal of Anspach Europe Ltd as EU Representative
Current	8941760	Renewal. Added product listing matrix. Change Subcontractor from Sterigenics to Sotera Health LLC.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.