

## EC DECLARATION OF CONFORMITY

### *Quill™ PDO (Polydioxanone)*

**Manufacturer (Name and Address)** : Surgical Specialties Mexico S. DE R.L. DE C.V.  
Corredor Tijuana-Rosarito 2000  
#24702-B, Ejido Francisco Villa,  
Tijuana, B.C., C.P. 22235, Mexico

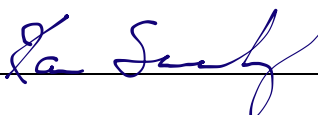
**European Authorized Representative if any (Name and Address)** : FSSB Chirurgische Nadln GmbH  
Allmendweg 2, 79798 Jestetten  
Germany

We herewith declare under our sole responsibility that the above mentioned product(s) to which this declaration relates, are in conformity with the European Directive 93/42/EEC for medical devices of 14 June 1993, as amended. As required by Annex II of the above Directive, this Declaration is supported by the EC Certificate and Surgical Specialties Mexico Technical File Documentation. In addition, the Quality System is certified as meeting the requirements of the harmonized standard EN ISO 13485:2016.

<b>Product Category:</b>	Quill™ PDO (Polydioxanone)		
<b>Product Name / Product Code:</b>	See listing below		
<b>GMDN/IDN:</b>	60480 / H0101010102		
<b>Product Classification:</b>	III	<b>Classification Rule:</b>	8
<b>Conformity Assessment Route:</b>	Annex II		
<b>Notified Body (Identification No.):</b>	SGS Belgium NV (1639) SGS House Noorderlaan 87 2030 Antwerp Belgium		
<b>Intended Use:</b>	The Quill™ PDO (Polydioxanone) products are indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.		

<b>Certification Type:</b>	<b>Certificate No.:</b>	<b>Validity:</b>
ISO 13485:2016 EN ISO 13485:2016	US01/53651	Until: 8 November 2022
Directive 93/42/EEC Annex II (excluding Section 4)	US19/819943658	Until: 24 May 2024
Directive 93/42/EEC Annex II Section 4	US19/819943622	Until: 24 May 2024

**Date of Issue/Update of Declaration** : 01 December 2021  
**Approved By - Name** : Karen Sanchez  
**Title** : Manager, Regulatory Affairs

**Signature** : 

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#### List of CE Marked Devices

This Declaration of Conformity applies to the following product codes:

#### **Quill™ PDO Knotless Tissue-Closure Device, Bi-Directional Products**

Product Code	Product Name	Brand	GTIN
RA-1000Q	PDO,Violet,0,14cm x 14cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018321
RA-1001Q	PDO,Violet,0,14cm x 14cm ,Reverse Cutting,OS-2,Bi-Directional	Quill™	848782018345
RA-1002Q	PDO,Violet,2-0,3.5cm x 3.5cm,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018369
RA-1003Q	PDO,Violet,1,14cm x 14cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018383
RA-1004Q	PDO,Violet,1,14cm x 14cm ,Reverse Cutting,CP-2,Bi-Directional	Quill™	848782018406
RA-1005Q	PDO,Violet,2,14cm x 14cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018420
RA-1006Q	PDO,Violet,2,14cm x 14cm ,Reverse Cutting,CP-2,Bi-Directional	Quill™	848782018444
RA-1007Q	PDO,Violet,2-0,7cm x 7cm,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018468
RA-1008Q	PDO,Violet,3-0,3.5cm x 3.5cm,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018482
RA-1010Q	PDO,Violet,3-0,7cm x 7cm,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018505
RA-1012Q	PDO,Violet,4-0,7cm x 7cm,Diamond Point,2xDE12,Bi-Directional	Quill™	848782018529
RA-1012Q-0	PDO,Violet,4-0,7cm x 7cm,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018536
RA-1013Q	PDO,Violet,2-0,7cm x 7cm,Tapercut,STC8,Bi-Directional	Quill™	848782018550
RA-1015Q	PDO,Violet,0,7cm x 7cm,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018574
RA-1016Q	PDO,Violet,2-0,7cm x 7cm,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018598
RA-1017Q	PDO,Violet,3-0,7cm x 7cm,Precision Reverse Cutting,P-1,Bi-Directional	Quill™	848782018611
RA-1019Q	PDO,Violet,0,14cm x 14cm ,Diamond Point,2xDE14,Bi-Directional	Quill™	848782018635
RA-1019Q-0	PDO,Violet,0,14cm x 14cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018642
RA-1020Q	PDO,Violet,2-0,14cm x 14cm ,Diamond Point,2xDE14,Bi-Directional	Quill™	848782018666
RA-1020Q-0	PDO,Violet,2-0,14cm x 14cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018673

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### *Quill™ PDO (Polydioxanone)*

Product Code	Product Name	Brand	GTIN
RA-1021Q	PDO,Violet,3-0,14cm x 14cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018697
RA-1023Q	PDO,Violet,0,7cm x 7cm,Tapercut,STC8,Bi-Directional	Quill™	848782018710
RA-1024Q	PDO,Violet,1,7cm x 7cm,Tapercut,STC8,Bi-Directional	Quill™	848782018734
RA-1028Q	PDO,Violet,2-0,24cm x 24cm ,Diamond Point,2xDE 14,Bi-Directional	Quill™	848782018758
RA-1028Q-0	PDO,Violet,2-0,24cm x 24cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018765
RA-1029Q	PDO,Violet,0,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018789
RA-1030Q	PDO,Violet,0,24cm x 24cm ,Diamond Point,2xDE 14,Bi-Directional	Quill™	848782018802
RA-1030Q-0	PDO,Violet,0,24cm x 24cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782018819
RA-1031Q	PDO,Violet,1,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018833
RA-1032Q	PDO,Violet,1,24cm x 24cm ,Reverse Cutting,CP-2,Bi-Directional	Quill™	848782018857
RA-1033Q	PDO,Violet,2,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782018871
RA-1034Q	PDO,Violet,2,24cm x 24cm ,Reverse Cutting,CP-2,Bi-Directional	Quill™	848782018895
RA-1036Q	PDO,Violet,2-0,24cm x 24cm ,Diamond Point,2xDE 12,Bi-Directional	Quill™	848782018918
RA-1036Q-0	PDO,Violet,2-0,24cm x 24cm ,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018925
RA-1046Q	PDO,Violet,2-0,14cm x 14cm ,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018949
RA-1050Q	PDO,Violet,3-0,14cm x 14cm ,Diamond Point,2xDE 12,Bi-Directional	Quill™	848782018963
RA-1050Q-0	PDO,Violet,3-0,14cm x 14cm ,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782018970
RA-1051Q	PDO,Violet,3-0,24cm x 24cm ,Diamond Point,2xDE 12,Bi-Directional	Quill™	848782018994
RA-1051Q-0	PDO,Violet,3-0,24cm x 24cm ,Precision Reverse Cutting,PS-2,Bi-Directional	Quill™	848782019007
RA-1052Q	PDO,Violet,3-0,24cm x 24cm ,Diamond Point,2xDE 14,Bi-Directional	Quill™	848782019021
RA-1052Q-0	PDO,Violet,3-0,24cm x 24cm ,Precision Reverse Cutting,PS,Bi-Directional	Quill™	848782019038
RA-1056Q	PDO,Violet,3-0,24cm x 24cm ,Diamond Point,2xDE 14,Bi-Directional	Quill™	848782019052
RA-1056Q-0	PDO,Violet,3-0,24cm x 24cm ,Reverse Cutting,CP-2,Bi-Directional	Quill™	848782019069
RA-1057Q	PDO,Violet,2-0,40cm x 40cm,Taper Point,SH,Bi-Directional	Quill™	848782019083

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Product Code	Product Name	Brand	GTIN
RA-1058Q	PDO,Violet,2,30cm x 30cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019106
RA-1059Q	PDO,Violet,1,30cm x 30cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019120
RA-1060Q	PDO,Violet,0,30cm x 30cm,Taper Point,CTX,Bi-Directional	Quill™	848782019144
RA-1065Q	PDO,Violet,2,36cm x 36cm,Taper Point,CTX,Bi-Directional	Quill™	848782019168
RA-1067Q	PDO,Violet,0,36cm x 36cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019182
RA-1077Q	PDO,Violet,2-0,10cm x 10cm,Taper Point,SH,Bi-Directional	Quill™	848782019205
RA-1078Q	PDO,Violet,0,10cm x 10cm,Taper Point,SH,Bi-Directional	Quill™	848782019212
RA-1079Q	PDO,Violet,0,14cm x 14cm ,Taper Point,SH,Bi-Directional	Quill™	848782019236
RA-1085Q	PDO,Violet,0,10cm x 10cm,Taper Point,S-18,Bi-Directional	Quill™	848782019250
RA-1086Q	PDO,Violet,2-0,14cm x 14cm ,Taper Point,SH-1,Bi-Directional	Quill™	848782019274
RA-1088Q	PDO,Violet,1,14cm x 14cm ,Taper Point,SH-1,Bi-Directional	Quill™	848782019281
RA-1090Q	PDO,Violet,0,45cm x 45cm,Reverse Cutting,PS-1,Bi-Directional	Quill™	848782000180
RA-2065Q	PDO,Violet,2,45cm x 45cm,Taper Point,CTX,Bi-Directional	Quill™	848782019304
RA-2067Q	PDO,Violet,0,45cm x 45cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019328
RA-2070Q	PDO,Violet,4-0,7cmx7cm,Taper Point,RB-1,Bi-Directional	Quill™	848782008186
RX-1029Q	PDO,Violet,0,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782019403
RX-1031Q	PDO,Violet,1,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782019427
RX-1033Q	PDO,Violet,2,24cm x 24cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782019441
RX-1058Q	PDO,Violet,2,30cm x 30cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019465
RX-1059Q	PDO,Violet,1,30cm x 30cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019489
RX-1062Q	PDO,Violet,2,36cm x 36cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019502
RX-1066Q	PDO,Violet,2,36cm x 36cm,Reverse Cutting,CP,Bi-Directional	Quill™	848782019526
RX-1068Q	PDO,Violet,0,7cm x 7cm,Taper Point,CT-1,Bi-Directional	Quill™	848782019540
RX-1069Q	PDO,Violet,0,14cm x 14cm ,Taper Point,CT-1,Bi-Directional	Quill™	848782019564

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<b>Product Code</b>	<b>Product Name</b>	<b>Brand</b>	<b>GTIN</b>
RX-2066Q	PDO,Violet,2,45cm x 45cm,Reverse Cutting,CP,Bi-Directional	Quill™	848782019588
RX-2068Q	PDO,Violet,0,45cm x 45cm,Reverse Cutting,CP-1,Bi-Directional	Quill™	848782019601
RX-2069Q	PDO,Violet,0,36cm x 36cm,Reverse Cutting,CP-1,Bi-Directional	Quill™	848782019625

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#### **Quill™ PDO Knotless Tissue-Closure Device, Uni-Directional Products**

Product Code	Product Name	Brand	UDI
VLP-1001	PDO, Violet, 0, 20cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020584
VLP-1002	PDO, Violet, 0, 30cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020607
VLP-1003	PDO, Violet, 0, 30cm, Taper Point, SH-1, Uni-Directional	Quill™	848782020621
VLP-1004	PDO, Violet, 0, 45cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020645
VLP-1005	PDO, Violet, 0, 20cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782020669
VLP-1006	PDO, Violet, 0, 30cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782020676
VLP-1007	PDO, Violet, 0, 20cm, Precision Reverse Cutting, PS, Uni-Directional	Quill™	848782020683
VLP-1008	PDO, Violet, 0, 20cm, Taper Point, SH-1, Uni-Directional	Quill™	848782020690
VLP-2001	PDO, Violet, 2-0, 45cm, Precision Reverse Cutting, PS-2, Uni-Directional	Quill™	848782020706
VLP-2002	PDO, Violet, 2-0, 30cm, Taper Point, SH-1, Uni-Directional	Quill™	848782020720
VLP-2005	PDO, Violet, 0, 30cm, Precision Reverse Cutting, PS, Uni-Directional	Quill™	848782020744
VLP-2006	PDO, Violet, 2-0, 20cm, Taper Point, SH, Uni-Directional	Quill™	848782020751
VLP-2008	PDO, Violet, 0, 20cm, Taper Point, SH, Uni-Directional	Quill™	848782020768
VLP-2009	PDO, Violet, 0, 30cm, Taper Point, SH, Uni-Directional	Quill™	848782020775
VLP-2010	PDO, Violet, 2, 70cm, Taper Point, CTX, Uni-Directional	Quill™	848782020782
VLP-2011	PDO, Violet, 2, 70cm, Reverse Cutting, CP, Uni-Directional	Quill™	848782020805
VLP-2012	PDO, Violet, 0, 70cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020829
VLP-2013	PDO, Violet, 1, 70cm, Taper Point, CT, Uni-Directional	Quill™	848782020843
VLP-2014	PDO, Violet, 1, 45cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020850
VLP-2015	PDO, Violet, 1, 30cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020867
VLP-2016	PDO, Violet, 2, 20cm, Taper Point, CT-1, Uni-Directional	Quill™	848782020874
VLP-2019	PDO, Violet, 2, 45cm, Precision Reverse Cutting, CP, Uni-Directional	Quill™	848782024575
VLP-2020	PDO, Violet, 2-0, 20cm, Taper Point, RB-1, Uni-Directional	Quill™	848782020881

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Product Code	Product Name	Brand	UDI
VLP-2021	PDO,Violet,2-0,15cm,Taper Point, SH, Uni-Directional	Quill™	848782023660
VLP-2022	PDO,Violet,2-0,15cm,Taper Point,RB-1,Uni-Directional	Quill™	848782023677
VLP-2024	PDO,Violet,2,70cm,Taper Point,CT-1,Uni-Directional	Quill™	848782024582
VLP-2025	PDO,Violet,2,45cm,Taper Point,CT-1,Uni-Directional	Quill™	848782024599
VLP-2026	PDO,Violet,2-0,45cm,Precision Reverse Cutting,PS-1,Uni-Directional	Quill™	848782024605
VLP-2027	PDO,Violet,2-0,60cm,Precision Reverse Cutting,PS-1,Uni-Directional	Quill™	848782024612
VLP-2028	PDO,Violet,1,20cm,Taper Point,CT-1,Uni-Directional	Quill™	848782024629
VLP-2029	PDO,Violet,3-0,45cm,Precision Reverse Cutting,PS-2,Uni-Directional	Quill™	848782024636
VLP-2030	PDO,Violet,2,15cm,Taper Point,CT-1,Uni-Directional	Quill™	848782024643
VLP-2031	PDO,Violet,2,60cm,Taper Point,TP-1,Uni-Directional	Quill™	848782024667
VLP-2032	PDO,Violet,2,30cm,Taper Point,CT-1,Uni-Directional	Quill™	848782024650
VLP-2033	PDO,Violet,2-0,30cm,Taper Point, SH, Uni-directional	Quill™	848782000173
VLP-2034	PDO,Violet,1,45cm,Taper Point, CTX, Uni-directional	Quill™	848782000203
VLP-2036	PDO,Violet,1,45cm,Taper Point,TP-1,Uni-directional	Quill™	848782000210
VLP-2037	PDO,Violet,2,45cm,Taper Point, CTX, Uni-directional	Quill™	848782000227
VLP-2038	PDO,Violet,0,45cm,Taper Point, SH, Uni-directional	Quill™	848782000234
VLP-2039	PDO,Violet,2-0,45cm,Taper Point, SH, Uni-directional	Quill™	848782000241
VLP-2040	PDO,Violet,2-0,45cm,Taper Point,CT-1,Uni-directional	Quill™	848782000258
VLP-2041	PDO,Violet,2-0,23cm,Taper Point,SKI-23,Uni-directional	Quill™	848782000326
VLP-2042	PDO,Violet,2-0,30cm,Taper Point,CT-1,Uni-directional	Quill™	848782000333
VLP-2043	PDO,Violet,3-0,20cm,Taper Point, SH, Uni-directional	Quill™	848782008179
VLP-2044	PDO,Violet,3-0,30cm,Taper Point, SH, Uni-directional	Quill™	848782000395
VLP-2045	PDO,Violet,3-0,15cm,Taper Point, SH, Uni-directional	Quill™	848782000401
VLP-2046	PDO,Violet,3-0,15cm,Taper Point,RB-1,Uni-directional	Quill™	848782000418

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Product Code	Product Name	Brand	UDI
VLP-2049	PDO, Violet, 2-0, 23cm, Taper Point, V-30, Uni-directional	Quill™	848782000449
VLP-2050	PDO, Violet, 2-0, 15cm, Taper Point, SH-1, Uni-directional	Quill™	848782000340
VLP-2051	PDO, Violet, 0, 15cm, Taper Point, SH, Uni-directional	Quill™	848782000357
VLP-2052	PDO, Violet, 2-0, 15cm, Taper Point, UR-6, Uni-directional	Quill™	848782000456
VLP-2053	PDO, Violet, 1, 30cm, Taper Point, UR-6, Uni-Directional	Quill™	848782004805
VLP-3021	PDO, Violet, 3-0, 20cm, Precision Reverse Cutting, P-3, Uni-Directional	Quill™	848782024483
VLP-3022	PDO, Violet, 3-0, 30cm, Precision Reverse Cutting, P-3, Uni-Directional	Quill™	848782024490
VLP-3026	PDO, Violet, 3-0, 20cm, Precision Reverse Cutting, PS-2, Uni-Directional	Quill™	848782024537
VLP-3027	PDO, Violet, 2-0, 20cm, Precision Reverse Cutting, PS-2, Uni-Directional	Quill™	848782024544
VLP-3028	PDO, Violet, 2-0, 30cm, Precision Reverse Cutting, PS-2, Uni-Directional	Quill™	848782024551
VLP-3029	PDO, Violet, 2-0, 30cm, Precision Reverse Cutting, PS-1, Uni-Directional	Quill™	848782024568
VLP-4109	PDO, Violet, 0, 15cm, Taper Point, RB-1, Uni-Directional	Quill™	848782037070
VLP-4132	PDO, Violet, 3-0, 30cm, Precision Reverse Cutting, PS-2, Uni-Directional	Quill™	848782037261
VLP-4133	PDO, Violet, 2, 45cm, Taper Point, CTX, Uni-Directional	Quill™	848782037278
VLP-4134	PDO, Violet, 1, 60cm, Reverse Cutting, OS-8, Uni-Directional	Quill™	848782037285
VLP-4135	PDO, Violet, 0, 30cm, Taper Point, CT-2, Uni-Directional	Quill™	848782037643
VLP-4136	PDO, Violet, 2-0, 15cm, Taper Point, CT-2, Uni-Directional	Quill™	848782037650
VLP-4137	PDO, Violet, 2-0, 20cm, Taper Point, CT-2, Uni-Directional	Quill™	848782037667
VLP-4138	PDO, Violet, 0, 45cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782040070
VLP-4140	PDO, Violet, 0, 70cm, Taper Point, CT-2, Uni-Directional	Quill™	848782040094
VLP-4142	PDO, Violet, 0, 70cm, Reverse Cutting, OS-6, Uni-Directional	Quill™	848782040100
VLP-4143	PDO, Violet, 0, 60cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782040117
VLP-4144	PDO, Violet, 1, 45cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782040124
VLP-4145	PDO, Violet, 0, 70cm, Taper Point, CT-1, Uni-Directional	Quill™	848782040131



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Product Code	Product Name	Brand	UDI
VLP-4146	PDO, Violet, 1,705cm, Reverse Cutting, CP-1, Uni-Directional	Quill™	848782040148