

DECLARATION OF CONFORMITY

Legal Manufacturer:	Beaver-Visitec International, Inc. 500 Totten Pond Road – 10 CityPoint Waltham, MA 02451 United States
Authorised Representative:	Vitrex B.V. Seggelant-Noord 2 3237 MG Vierpolders. The Netherlands
Products:	Specialty Blades, Knives and single use accessories (Product Code Listing attached)
Classification:	Specialty Blades and Knives, including Swivel Fixation Ring 372242, Class IIa. Rule 6; Teflon Block 9729 is Class I, Rule 1
Conformity Assessment Route:	Specialty Blades and Knives, Annex II (Full Quality Assurance) and Annex VII (Class I, Self-Declaration)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Council Directive 2007/47/EC of 5 September 2007. All supporting documentation is retained under the premises of the manufacturer, who is exclusively responsible for this Declaration of Conformity.

List of Harmonized/Other Standards:	EN ISO 13485:2016, EN 556-1:2001, BS EN ISO 14644-1:2015, EN ISO 15223-1:2016, ISO 8601:2016, EN ISO 14971:2012, EN ISO 10993-1:2009, EN ISO 14155-1:2011, EN 1041:2008, EN ISO 11137-1:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11135:2007
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany
Notified Body Number:	0123
EC Certificate number:	G1 103871
Start of CE marking:	N/A

Signed:



Regina Shih
Global Vice President Quality and Regulatory
Waltham, MA

Date

June 20, 2019

Products covered under Declaration of Conformity for Specialty Blades, and Knives:

Cat. No.	Description
BEAVER6400	Beaver® Mini-Blade
BEAVER6600	Beaver® Lamellar Blade, 60°, bevel up
BEAVER6610	Beaver® Lamellar Blade, sharp all around
BEAVER6700	Beaver® Mini-Blade
BEAVER6900	Beaver® Mini-Blade
BEAVER6910	Beaver® Cleft Palate Blade 60°
364820	Beaver® Mini-Blade , Bulk Sterile
364822	Beaver® Mini-Blade , Bulk Sterile
364823	Beaver® Mini-Blade , Bulk Sterile
370145	Beaver® Xstar Safety Slit Knife 2.5 mm 45° Bevel Up
370146	Beaver® Xstar Safety Slit Knife 2.6 mm 45° Bevel Up
370157	Atomic Edge® Safety Slit Knife 3.0mm
370159	Atomic Edge® Safety Slit Knife 2.8mm
370225	Atomic Edge® Safety Accurate Depth Knife 250 micron
370230	Atomic Edge® Safety Accurate Depth Knife 300 micron
370235	Atomic Edge® Safety Accurate Depth Knife 350 micron
370240	Atomic Edge® Safety Accurate Depth Knife 400 micron
370250	Atomic Edge® Safety Accurate Depth Knife 500 micron
370255	Atomic Edge® Safety Accurate Depth Knife 550 micron
370260	Atomic Edge® Safety Accurate Depth Knife 600 micron
370262	Atomic Edge® Safety Accurate Depth Knife 625 micron
370265	Atomic Edge® Safety Accurate Depth Knife 650 micron
370410	Beaver® Neuro-Sharp Blade Boyonet Sickle
370420	Beaver® Neuro-Sharp Blade, Bayonet Arachnoid
370820	Beaver® Xstar Slit Knife 2.0mm 45° Double Bevel Slit
370822	Beaver® Xstar Slit Knife 2.2mm 45° Double Bevel
370824	Beaver® Xstar Slit Knife 2.4mm 45° Double Bevel
370825	Beaver® Xstar Slit Knife 2.5mm 45° Double Bevel
370826	Beaver® Xstar Slit Knife 2.65mm 45° Double Bevel
370827	Beaver® Xstar Slit Knife 2.75mm 45° Double Bevel
370828	Beaver® Xstar Slit Knife 2.8mm 45° Double Bevel
370830	Beaver® Xstar Slit Knife 3.0mm 45° Double Bevel
371400	Beaver® Bent Blade, 45 degrees, sharp all around
372242	Beaver® Swivel Fixation Ring
373025	Beaver® Xstar Kojo Safety Slit 2.5 mm 45° Bevel Up
373032	Beaver® Xstar Kojo Safety Slit 3.2 mm 45° Bevel Up
373328	Beaver® Xstar Slit Knife, 2.8mm, straight
373330	Beaver® Xstar Slit Knife, 3.0mm, straight
373332	Beaver® Xstar Slit Knife, 3.2mm, straight
373432	Beaver® Xstar Implant Knife, 3.2mm, 45° Bevel Up
373710	Beaver® Sideport Knife, 1 mm 45°
373712	Beaver® Sideport Knife, 1.2mm 45°
373718	Beaver® Xstar Slit Knife 1.8mm 45° Bevel Up
373722	Beaver® Xstar Slit Knife 2.2mm 45° Bevel Up

373724	Beaver® Xstar Slit Knife 2.4mm 45° Bevel Up
373725	Beaver® Xstar Slit Knife 2.5mm 45° Bevel Up
373726	Beaver® Xstar Slit Knife 2.6mm 45° Bevel Up
373727	Beaver® Xstar Slit Knife 2.75mm 45° Bevel Up
373728	Beaver® Xstar Slit Knife 2.8mm 45° Bevel Up
373730	Beaver® Xstar Slit Knife 3.0mm 45° Bevel Up
373732	Beaver® Xstar Slit Knife 3.2mm 45° Bevel Up
373741	Beaver® Xstar Implant Knife 4.1mm 45° Bevel Up
373752	Beaver® Xstar Implant Knife, 5.2mm, 45 ° Bevel Up
373807	Beaver® Xstar Crescent Knife, 2.5mm, 55° Bevel Up
373808	Beaver® Xstar Crescent Knife, 2.5mm, 55° Straight
373809	Beaver® Xstar Crescent Knife, 2.5mm, 55° Bevel Down
374410	Beaver® Debakey Blade 5mm
374562	Beaver® Mini-Blade
374580	Beaver® Arthro-Lok Hoe 60° 4mm Blade
374710	Beaver® Debakey Blade 8mm
374755	Beaver® Pocket™ Scleral Knife 2.25mm 60°
374769	Beaver® Mini-Blade® Surgical Blade 180°
374810	Beaver® Debakey Blade 10mm
374821	Beaver® Mini Blade® Contains 100 Blades 376500
374881	Beaver® Optimum™ Blade 15° Straight
374882	Beaver® Optimum™ Blade 22.5° Straight
374883	Beaver® Optimum™ Blade 30° Straight
374884	Beaver® Optimum™ Blade 45° Straight
374890	Beaver® Optimum™ Sideport Knife 15° Bent Left 30°
374891	Beaver® Optimum™ Knife straight, 15°
374892	Beaver® Optimum™ Sideport Straight Knife, 22.5°
374893	Beaver® Optimum™ Sideport Straight Knife, 30°
374894	Beaver® Optimum™ Sideport Straight Knife, 45°
374900	Beaver® Mammoplasty Blade, 270°
375100	Beaver® Cataract Blade 19.0mm L x 1.4mm W
375210	Beaver® Cataract Blade, 20.5mm L x 1.7mm W
375220	Beaver® Cataract Blade, 25.5mm L x 2.2mm W
375435	Beaver® Beaverguard™ Guarded .35mm Depth Blade
375450	Beaver® Beaverguard™ Guarded .50mm Depth Blade
375505	Beaver® Slit Blade 1.5mm, Straight
375700	Beaver® Sclerotome™ Blade, Multi Sided
375701	Beaver® Sclerotome™ Blade, sharp all around
375910	Beaver® Needle Blade 3.0mm Cutting Edge
375920	Beaver® Needle Blade 5.0mm Cutting Edge
375930	Beaver® Needle Blade, 7.0mm Cutting Edge
375940	Beaver® Needle Blade 1.5mm Cutting Edge
376083	Beaver® Arthro-Lok® Retrograde 4mm Blade
376086	Beaver® Arthro-Lok® Pointed Retrograde 4mm Blade
376100	Beaver® Mini-Blade®
376300	Beaver® Mini-Blade®

376401	Beaver® Mini MIS 6400
376480	Beaver® Arthro-Lok®, Round Tip 4mm Blade
376481	Beaver® Arthro-Lok®, Round Tip 4mm Blade (Flat)
376482	Beaver® Arthro-Lok®, Round Tip 4mm Blade
376500	Beaver® Mini-Blade®
376620	Beaver® Sideport Knife 1.15mm 45°
376780	Beaver® Arthro-Lok®, Pointed Tip Curve L, 4mm Blade
376800	Beaver® Tonsillectomy Blade
376980	Beaver® Arthro-Lok®, Mini-banana 4mm Blade
376981	Beaver® Mini-Banana Blade (Flat) 4mm
376984	Beaver® Arthro-Lok® Banana 4mm Blade
377081	Beaver® ArthroLok® Rosette 4mm Blade
377100	Beaver® Myringotomy Blade Downcutting Tip 45°
377110	Beaver® Myringotomy Blade Upcutting Tip, 45°
377120	Beaver® Myringotomy Blade, Offset 45°
377121	Beaver® Myringotomy Blade Narrow Shaft Offset 45°
377122	Beaver® Spear Tip Myringotomy Knife 45°
377124	Beaver® Myringotomy Knife, Lance Tip 45°
377200	Beaver® Tympanoplasty Blade, 2.5mm W, 60° Bevel Down
377210	Beaver® Tympanoplasty Blade, 2.5mm W Straight
377300	Beaver® Sickle Edge Blade 5.0mm
377511	Beaver® Micro-Sharp Blade, 1.5 mm 15°
377512	Beaver® Micro-Unitome Knife, 1.5mm 15°
377513	Beaver® Micro-Sharp Blade 3.0mm 15°
377514	Beaver® Micro-Unitome Knife 3.0mm 15°
377515	Beaver® Micro-Sharp Blade 5.0mm 15°
377516	Beaver® Micro-Unitome, Knife 5.0mm 15°
377522	Beaver® Micro-Sharp Blade 4.0mm, 22.5°
377523	Beaver® Micro-Unitome Knife 4.0mm, 22.5°
377530	Beaver® Micro-Sharp Blade 3.5mm , 30°
377531	Beaver® Micro-Unitome Knife 3.5mm 30°
377546	Beaver® Micro-Unitome Knife 3.0mm 45°
377615	Beaver® Micro-Blade 15°
378100	Beaver® Chisel Blade
378210	Beaver® Safety Sideport Knife 1.0mm 45°
378212	Beaver® Safety Sideport Knife 1.2mm 45°
378214	Beaver® Xstar Safety Slit Knife 1.4mm 45° Bevel Up
378215	Beaver® Xstar Safety Slit Knife 1.5mm 45° Bevel Up
378217	Beaver® Xstar Safety Slit Knife 1.7mm 45° Bevel Up
378218	Beaver® Xstar Safety Slit Knife 1.8mm 45° Bevel Up
378220	Beaver® Xstar Safety Slit Knife 2.0mm 45° Bevel Up
378222	Beaver® Xstar Safety Slit Knife 2.2mm 45° Bevel Up
378223	Beaver® Xstar Safety Slit Knife 2.3mm 45° Bevel Up
378224	Beaver® Xstar Safety Slit Knife 2.4mm 45° Bevel Up
378227	Beaver® Xstar Safety Slit Knife 2.7mm 45° Bevel Up
378228	Beaver® Xstar Safety Slit Knife 2.8mm 45° Bevel Up

378230	Beaver® Xstar® Safety Slit Knife 3.0 mm 45° Bevel Up
378231	Beaver® Safety Sideport Knife 1.15mm 45°
378232	Beaver® Xstar® Safety Slit Knife 3.2 mm 45° Bevel Up
378234	Beaver® Xstar® Safety Crescent 2.5mm 55° Bevel Up
378235	Beaver® Optimum™ Safety Sideport Knife Straight 15°
378236	Beaver® Optimum™ Safety Sideport Knife Straight 22.5
378237	Beaver® Optimum™ Safety Sideport Knife Straight 30°
378238	Beaver® Optimum™ Safety Sideport Knife Straight 45°
378300	Beaver® Chisel Blade
378400	Beaver® Chisel Blade
378800	Beaver® Chisel Blade
378820	Beaver® Xstar® Safety Slit Knife, 2.0mm 45° Double Bevel Slit
378822	Beaver® Xstar® Safety Slit Knife [Osher], 2.2mm 45° Double Bevel
378824	Beaver® Xstar® Safety Slit Knife [Osher], 2.4mm 45° Double Bevel
378825	Beaver® Xstar® Safety Slit Knife [Osher], 2.5mm 45° Double Bevel
378826	Beaver® Xstar® Safety Slit Knife, 2.65mm 45° Double Bevel
378827	Beaver® Xstar® Safety Slit Knife, 2.75mm 45° Double Bevel
378828	Beaver® Xstar® Safety Slit Knife, 2.8mm 45° Double Bevel
378829	Beaver® Xstar® Safety Slit Knife, 2.85mm 45° Double Bevel
378830	Beaver® Xstar® Safety Slit Knife, 3.0mm 45° Double Bevel
378832	Beaver® Xstar® Safety Slit Knife, 3.2mm 45° Double Bevel
379081	Beaver® Arthro-Lok® Mini-Meniscus 4mm Blade (Flat)
379082	Beaver® Arthro-Lok® Mini-Meniscus 4mm Blade
379100	Beaver® Cervical Biopsy Blade
0001520	Beaver® Micro Knife, 5.0mm, 15°
0001521	Beaver® Micro Knife, 5.0mm, 22.5°
0001522	Beaver® Micro Knife, 5.0mm, 30°
0001523	Beaver® Micro Knife, 5.0mm, 45°
0009701	Beaver® Corneal Trephine Blade 5.0mm
0009703	Beaver® Corneal Trephine Blade 5.5mm
0009705	Beaver® Corneal Trephine Blade 6.0mm
0009706	Beaver® Corneal Trephine Blade 6.25mm
0009707	Beaver® Corneal Trephine Blade 6.5mm
0009708	Beaver® Corneal Trephine Blade 6.75mm
0009709	Beaver® Corneal Trephine Blade 7.0mm
0009710	Beaver® Corneal Trephine Blade 7.85mm
0009711	Beaver® Corneal Trephine Blade 7.5mm
0009713	Beaver® Corneal Trephine Blade, 8.0mm
0009715	Beaver® Corneal Trephine Blade, 8.5mm
0009717	Beaver® Corneal Trephine Blade, 9.0mm
0009719	Beaver® Corneal Trephine Blade 7.25mm
0009721	Beaver® Corneal Trephine Blade, 10.0mm
0009722	Beaver® Corneal Trephine Blade, 7.75mm
0009723	Beaver® Corneal Trephine Blade 8.75mm
0009725	Beaver® Corneal Trephine Blade 11.0mm
0009727	Beaver® Corneal Trephine Blade 8.25mm

0009728	Beaver® Corneal Trephine Blade 14.0mm
9550005	Beaver® Corneal Trephine Blade 9.5mm
9550006	Beaver® Corneal Trephine Blade 10.5mm
9550013	Beaver® Corneal Trephine Blade 11.5mm
9550025	Beaver® Corneal Trephine Blade 9.25mm
9550026	Beaver® Corneal Trephine Blade 4.0mm
9550028	Beaver® Corneal Trephine Blade 12.0mm
9550029	Beaver® Corneal Trephine Blade 13.0mm
9729	Beaver® Replacement Teflon Block Used with 1728

HISTORY SHEET

Effective Date	DESCRIPTION	INITIATOR
1/27/10	DOC separated from Technical File RTF30. The Declaration of Conformity will be it own date controlled document. Updated formatting. Added Catalog Numbers 373718, 373722, & 373724.	D. Puma
4/30/2010	Removed Catalog Numbers 375025, 375030, 375035, 375050, 375055, 375060 and correct numerical order of cat #'s, added 376700 to listing	G.Moushigian
6/25/10	Added Catalog Numbers: 370822, 370824, 370825, 370826, 370827, 370828, 370830 to listing	D. Puma
8/9/10	Removed Catalog Numbers 371600 & 374103 – Rationalized product.	D. Puma
10/04/2010	Update Manufacture, Authorized Rep and Mfg. Site Names, EC Cert Number , remove “BD” from Product/Classification/and Conformity blocks and added new Non-Safety XStar Product codes, deleted 376100 discontinued; corrected Notified Body Name and added Notified Body Number	G.Moushigian
10/20/2010	Removed 376630, part of Bidford technical file for knives, added 376100 Mini-Blade	G. Moushigian
3/16/2011	Correct EC Cert # from GB10/81383 to US10/81383	G.Moushigian
5/05/2011	Added BEAVER6400, BEAVER6600, BEAVER 6610, BEAVER6700, BEAVER6900, BEAVER6910	G.Moushigian
9/21/2011	Corrected in Classification : Specialty Blades and Knives Class IIA to Class Ila	G.Moushigian
9/28/2011	Add Catalog Number 378220 to listing	G.Moushigian
2/12/2011	Removed the following Catalog Numbers due to discontinuation: 370110, 370120, 370307, 370327, 370328, 370330, 370332, 370341, 370391, 370392, 370393, 370394, 371800, 373341, 373352, 374524, 374736, 374761, 376806, 375500, 375504, 375510, 375523, 375570, 376782, 376981, 377000, 379071, 379710	G.Moushigian
3/23/2012	Add Catalog Number 364820, 364822, 364823, 378223 to listing	G.Moushigian
7/18/2012	Add Catalog Number 376891	D. Cromwick
8/01/2012	Added Atomic Edge Trepine Blasé and Micro knives , removed Ring Cutter and Handles	G.Moushigian
8/01/2012	Added Cat #'s 373710 and 378210	G.Moushigian
12/05/2012	Added Cat #'s RD0141, RD0142, RD0221, RD0222, and RD2225	G.Moushigian

	For user assessment only	
2/19/2013	Update Signature block(Name and Title)	G.Moushigian
3/01/2013	Corrected all descriptions and removed Cat #'s RD0141, RD0142, RD0221, RD0222, and RD2225 to a separate DOC	G.Moushigian
5/24/2013	Remove Obsolete Cat#'s 373735 and 376320	G.Moushigian
11/20/2013	Added Cat # 378212	G.Moushigian
7/10/2014	Correct Description of Product Codes 370822, 370824, 370825, 370826, 370827, 370828, 370830, 378234, 370145, 370146	G.Moushigian
7/21/2014	Correct Description of Product Codes 370145, 370146	G.Moushigian
8/18/2014	Corrected title to add ... and single use accessories; Added Product Codes 372242 and 9729	G.Moushigian
10/30/2014	Correct Description of Product Code 373808 (added 55°)	G.Moushigian
12/17/2014	Correct Description of Product Codes 373432, 374881, and 374890	G.Moushigian
01/06/2015	Remove the word [Osher] from the description of 378826, 378827, 378828, 378829, 378830, 378832	G.Moushigian
01/14/2015	Remove Cat # 379400, 379500 and 379700 discontinued	G.Moushigian
11/30/2015	Change Class from II to IIa	G.Moushigian
3/25/2016	Remove Discontinue Part# 373435	G.Moushigian
11/29/16	Added new part # 373712	D. Hebert
5/11/2017	Remove Discontinue Part# 374451 and Amended EC statement	G.Moushigian
7/13/2017	Amend statement of conformity; delete Manufacturing Site and Assembly Site; add place of issue per ISO/IEC 17050-1; remove discontinued Cat#'s 376400, 376700, 376900 and 376910	G. Moushigian
5/24/2018	Legal manufacturing site address and logo updated	J. Shah
8/6/2018	Removed Discontinue Parts 375516, 377630, 378600	G.Moushigian
4/25/2019	Changed EU Rep from BVI Bidford to Vitreq; updated standards, notified body to TUV, EC certificate number, and manufacturer's statement. Removed discontinued parts: 373835, 374520, 377545, 374723, 374751, 374752, 374756, 374805, 374822, 374823, 375520, 375521, 375522, 376600, 376610, 374820.	J. Shah
6/19/2019	Add New Cat#'s 370820 and 378820	G.Moushigian