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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|
| <br><b>Declaration of EU conformity</b><br><b>PTD-W003 (RTF26)</b><br><b>Class IIa, Rev. 04</b> | <b>Document Number</b> | IFM988, Rev. 06    |
|                                                                                                                                                                                  | <b>Valid from</b>      | <b>25 May 2021</b> |
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## DECLARATION OF EU CONFORMITY

**CE Manufacturer:**  
**Address:**

**Beaver-Visitec International Inc**  
**500 Totten Pond Road**  
**10 CityPoint**  
**Waltham Massachusetts 02451**  
**USA**

**Product name/Identifier:** Cannula, Cystotome and Needle Range (Product code listing attached)

**Classification and Rule according to MDD 93/42/EEC per Annex IX Implementation Rules:**

- **Class IIa, Rule 6**

We hereby declare under our exclusive responsibility that the above-named medical device(s) meet(s) the provisions of European Medical Device Directive MDD 93/42/EEC as well as other applicable laws, regulations and directives. Conformity assessment of the medical device(s) is done following route of **MDD 93/42/EEC Annex II (excluding 4) (Full Quality Assurance)**. Design and manufacturing are in compliance with the applicable harmonized Standards published in the Official Journal of the European Union. When used under the conditions and purposes intended, the above-named medical device(s) will not compromise the clinical conditions or safety of patients, users or other persons.

**Applied harmonized standards:**

**EN ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 11737-1, EN ISO 11737-2, EN ISO 13485, EN 556-1, EN ISO 11137-1, EN ISO 11137-2, EN ISO 14971, EN ISO 15223-1, EN 1041.**

**CE-application of the above-named medical devices(s) was solely done at notified body:**

TÜV SÜD Product Service GmbH  
Notified body N° 0123  
Ridlerstraße 65, 80339 München, Germany

**Authorized Representative:**

Vitrex B.V. Seggelant-Noord 2  
3237 MG Vierpolders,  
The Netherlands

**Related certificates:**

ISO 13485: 2016 N°Q5 103871 0004 Rev. 00, valid until: 2023-12-13  
EC Certificate **Annex II excluding (4)** N°G1 103871 0008 Rev. 00, valid until: 2024-05-26  
GS MDSAP (ISO 13485 2016) US19 87841492 EXP 2022-04-02

**Date of first market entry:** 2010-08-01

**Place / Date:** Waltham, MA, USA /2021-05-25

**Signature:**  \_

**Name:** Robin L. Rowe, MSc, RAC

**Position:** Sr. Director, Regulatory & Medical Affairs

|                                                                                                                                                                                  |                        |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|
| <br><b>Declaration of EU conformity</b><br><b>PTD-W003 (RTF26)</b><br><b>Class IIa, Rev. 04</b> | <b>Document Number</b> | IFM988, Rev. 06    |
|                                                                                                                                                                                  | <b>Valid from</b>      | <b>25 May 2021</b> |
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Table 1 Product representation

| <b>Product code (Cat. No.)</b> | <b>Product Description</b>                                                         | <b>GMDN Code</b> |
|--------------------------------|------------------------------------------------------------------------------------|------------------|
| 581012                         | Visitec® Irrigation Handle 9.3cm (3 5/8 in)                                        | 46724            |
| 581097                         | Visitec® Flute Cannula [Charles] .90 x 28mm (20G x 1 1/8 in)                       | 46705            |
| 581273                         | Visitec® Anterior Chamber Cannula (Rycroft) .30 x 22mm (30G x 7/8in)               | 46705            |
| 581275                         | Visitec® Retrobulbar [Sharp Point] .50 x 38mm (25G x 1 1/2 in)                     | 59230            |
| 581276                         | Visitec® Lacrimal Cannula .45 x 28mm (26G x 1 1/8 in)                              | 46705            |
| 581280                         | Visitec® Anterior Chamber Cannula (Rycroft) .40 x 22mm (27G x 7/8in)               | 46705            |
| 581281                         | Visitec® Anterior Chamber Cannula (Rycroft) .80 x 22mm (21G x 7/8in)               | 46705            |
| 581284                         | Visitec® Anterior Chamber Cannula (Rycroft) .40 x 22mm (27G x 7/8in) 6mm Bend      | 46705            |
| 581285                         | Visitec® Anterior Chamber Cannula (Rycroft) .30 x 22mm (30G x 7/8in) 6mm Bend      | 46705            |
| 581594                         | Visitec® Irrigating Cystotome .60 x 16mm (25G x 5/8 in)                            | 46705            |
| 581599                         | Irrigating Cystotomes .60 x 16 mm (23G x 5/8 in)                                   | 46705            |
| 581602                         | Irrigating Cystotomes Side Cutting Irrigating Cystotome .50 x 16 mm (25G x 5/8 in) | 46705            |
| 581610                         | Irrigating Cystotome [Pearce] .50 x 16 mm (25G x 5/8 in)                           | 46705            |
| 581617                         | Irrigating Cystotome .50 x 16 mm (25G x 5/8 in)                                    | 46705            |
| 581618                         | Irrigating Cystotome .40 x 16 mm (27G x 5/8 in)                                    | 46705            |
| 581630                         | Irrigating Cystotome .30 x 16 mm (30G x 5/8 in)                                    | 46705            |
| 581637                         | Visitec® Retrobulbar [Atkinson] .50 x 38mm (25G x 1 1/2 in)                        | 59230            |
| 581638                         | Visitec® Retrobulbar [Atkinson] .60 x 38mm (23G x 1 1/2 in)                        | 59230            |
| 581639                         | Visitec® Anterior Chamber Cannula (Rycroft) .50 x 22mm (25G x 7/8in)               | 46705            |
| 581640                         | Visitec® Retrobulbar (Sharp) [Atkinson] .60 x 38mm (23G x 1 1/2 in)                | 59230            |
| 581641                         | Visitec® Retrobulbar (Sharp) [Atkinson] .50 x 38mm (25G x 1 1/2 in)                | 59230            |
| 581642                         | Visitec® Anterior Chamber Cannula (Rycroft) .50 x 22mm (25G x 7/8in) 6mm Bend      | 46705            |
| 585001                         | Visitec® Retrobulbar/Peribulbar [Atkinson] .60 x 32mm (23G x 1 1/4 in)             | 59230            |
| 585003                         | Visitec® Micro J Shape Cannula .50 x 22mm (25G x 7/8 in)                           | 46705            |
| 585005                         | Visitec® Flexible Tip Cannula .40 x 22mm (27G x 7/8 in)                            | 46705            |
| 585006                         | Visitec® Anterior Chamber Cannula .40 x 22mm (27G x 7/8in)                         | 46705            |
| 585007                         | Visitec® Viscoflow® Cannula [Formed] .40 x 22mm (27G x 7/8 in)                     | 46705            |
| 585009                         | Visitec® Viscoflow® Cannula .60 x 22mm (23G x 7/8)                                 | 46705            |
| 585017                         | Visitec® Flexible Tip Cannula .50 x 22mm (25G x 7/8 in)                            | 46705            |
| 585018                         | Visitec® Micro J Shape Cannula .40 x 22mm (27G x 7/8 in)                           | 46705            |

Vertimas iš anglų k



## Atitikties deklaracija

Gamintojas: Beaver-Visitec International, Inc.  
Adresas: 500 Totten Pond Road  
10 CityPoint  
Waltham Massachusetts 02451  
JAV

**Produkto pavadinimas/identifikatorius: Kaniulė, cistotomas ir adatų asortimentas (gaminio kodų sąrašas pridedamas)**

**Klasifikavimas ir taisyklės pagal MDD 93/42/EEB pagal IX priedą įgyvendinimo taisyklės: IIa klasė, 6 taisyklė**

Mes prisiimame visą atsakomybę, kad aukščiau minėtas (-i) medicinos prietaisas (-ai) atitinka Europos medicinos prietaisų direktyvos MDD 93/42/EEB ir kitų galiojančių įstatymų, reglamentų ir direktyvų nuostatas. Medicinos prietaiso (-ų) atitikties vertinimas atliekamas pagal MDD 93/42/EEB II priedą. Projektavimas ir gamyba atitinka taikomus darniuosius standartus, paskelbtus Europos Sąjungos oficialiajame leidinyje.

Naudojant aukščiau nurodytą (-as) medicinos prietaisą (-us) numatytomis sąlygomis ir tikslais, tai nepakenks pacientų, naudotojų ar kitų asmenų klinikinėms sąlygoms ar saugumui.

**Taikomi suderinti standartai: EN ISO 10993-1, EN ISO 15223-1, EN ISO 13485, EN 556-1, EN ISO 14971, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN 1041.**

**Aukščiau nurodytų medicinos prietaisų CE taikymas buvo atliktas tik notifikuotojoje įstaigoje:**

TÜV SÜD Product Service GmbH  
Notified body N° 0123  
Ridlerstraße 65, 80339 Miunchenas, Vokietija

**Įgaliotasis atstovas:**

Vitrex B.V. Seggelant-Noord 2  
3237 MG Vierpolders,  
Olandija

**Susiję sertifikatai:**

EN ISO 13485: 2016: Nr. Q5 103871 0004 Rev. 00, Galioja iki: 2023-12-13  
EB sertifikatas: II priedas, Nr. G1 103871 0008 Rev. 00 Galioja iki: 2024-05-26  
GS MDSAP (ISO 13485 2016) US19/81841492 Galioja iki: 2022-04-02

Pirmojo įėjimo į rinką data: 2010-08-01  
Vieta / data: Waltham, MA, USA / 2021-05-25.

Parašas: \_\_\_\_\_  
Vardas: Robin L. Rowe, MSc, RAC  
Pareigos: Medicinos priežiūros ir kontrolės direktorius

| <i><b>Product<br/>code<br/>(Cat.<br/>No.)</b></i> | <i><b>Product Description</b></i>                                               | <i><b>GMDN<br/>Code</b></i> |
|---------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------|
| 585025                                            | Visitec® Anterior Chamber Cannula (Rycroft) .60 x 22mm (23G x 7/8in)            | 46705                       |
| 585026                                            | Visitec® Viscoflow® Cannula .40 x 22mm (27G x 7/8 in)                           | 46705                       |
| 585027                                            | Visitec® Peribulbar [Atkinson] .50 x 22mm (25G x 7/8 in)                        | 59230                       |
| 585036                                            | Visitec® Nucleus Hydrodissector [Pearce] .40 x 22mm (27G x 7/8 in)              | 46705                       |
| 585037                                            | Visitec® Nucleus Hydrodissector [Pearce] .50 x 22 mm (25G x 7/8 in)             | 46705                       |
| 585041                                            | Visitec® Flexible Tip Cannula .60 x 22mm (23G x 7/8 in)                         | 46705                       |
| 585045                                            | Visitec® Viscoflow® Cannula .50 x 22mm (25G x 7/8 in)                           | 46705                       |
| 585046                                            | Visitec® Viscoflow® Cannula .30 x 22mm (30G x 7/8 in)                           | 46705                       |
| 585068                                            | Visitec® Lacrimal Cannula .50 x 13mm (25G x 1/2 in)                             | 46705                       |
| 585099                                            | Visitec® Nucleus Hydrodissector [Sauter] .40 x 22mm (27G x 7/8 in)              | 46705                       |
| 585108                                            | Visitec® Retrobulbar/Peribulbar [Atkinson] .50 x 32mm (25G x 1 1/4 in)          | 59230                       |
| 585109                                            | Visitec® Retrobulbar/Peribulbar [Atkinson] .40 x 32mm (27G x 1 1/4 in)          | 59230                       |
| 585119                                            | Visitec® Infusion Cannula 4mm .90mm (20G)                                       | 46705                       |
| 585120                                            | Visitec® Infusion Cannula 6mm .90mm (20G)                                       | 46705                       |
| 585144                                            | Visitec® Peribulbar [Atkinson] .60 x 22mm (23G x 7/8 in)                        | 47017                       |
| 585145                                            | [Atkinson] .40 x 22mm (27G x 7/8 in)                                            | 47017                       |
| 585155                                            | Visitec® Nucleus Hydrodissector .40 x 22mm (27G x 7/8 in)                       | 46705                       |
| 585157                                            | Visitec® Cortical Cleaving Hydrodissector (Round End) .40 x 22mm (27G x 7/8 in) | 46705                       |
| 585158                                            | Visitec® Cortical Cleaving Hydrodissector (Flat End) .40 x 22mm (27G x 7/8 in)  | 46705                       |
| 585173                                            | Visitec® High Viscosity Injector 4mm [Hammer] .90mm 20G                         | 46705                       |
| 585184                                            | Visitec® High Viscosity Injector 6mm [Hammer] .90mm 20G                         | 46705                       |
| 585205                                            | Visitec® Vitreoretinal Cannula .90 x 28mm (20G x 1 1/8 in)                      | 46705                       |
| 585208                                            | Visitec® High Viscosity Injector 4mm [Hammer] .90mm 20G                         | 46705                       |
| 585226                                            | Visitec® Soft Tip Cannula .60 x 33mm (23G x 1.3 in) 3mm tip                     | 46705                       |
| 585228                                            | Visitec® High Viscosity Injector 6mm [Hammer] .90mm 20G (16cm tube)             | 46705                       |
| 585229                                            | Visitec® Soft Tip Cannula .50 x 33mm (25G x 1.3 in) 3mm tip                     | 46705                       |
| 585238                                            | Visitec® Viscoflow® Cannula .60 x 22mm (23G x 7/8 in)                           | 46705                       |
| 585278                                            | Visitec® LASIK Irrigating Cannula .40 x 22mm (27G x 7/8 in)                     | 46705                       |
| 585281                                            | Visitec® Viscoflow® Cannula .50 x 22mm (25G x 7/8 in)                           | 46705                       |
| 585282                                            | Visitec® Viscoflow® Cannula .40 x 22mm (27G x 7/8 in)                           | 46705                       |
| 585288                                            | Visitec® Viscoflow® Cannula .50 x 22mm (25G x 7/8 in)                           | 46705                       |
| 585291                                            | Visitec® Viscoflow® Cannula .40 x 22mm (27G x 7/8 in)                           | 46705                       |
| 585292                                            | Visitec® Viscoflow® Cannula 25° Thin Wall .50 x 22mm (25G x 7/8 in)             | 46705                       |
| 585611                                            | Visitec® Retrobulbar [Atkinson] .50 x 38mm (25G x 1 1/2 in)                     | 59230                       |
| 587002                                            | Visitec® Soft Tip Cannula 0.8 .60 x 33mm (23G x 1.3 in)                         | 46705                       |
| 587003                                            | Visitec® Soft Tip Cannula 0.8 .50 x 33mm (25G x 1.3 in)                         | 46705                       |