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|  | Document Number | IFM988, Rev. 06 |
| | Declaration of EU conformity PTD-W003 (RTF26) Class IIa, Rev. 04 | Valid from |
| | Page | Page 1 of 3 |

DECLARATION OF EU CONFORMITY

CE Manufacturer: Beaver-Visitec International Inc
Address: 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:

Vitreq 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

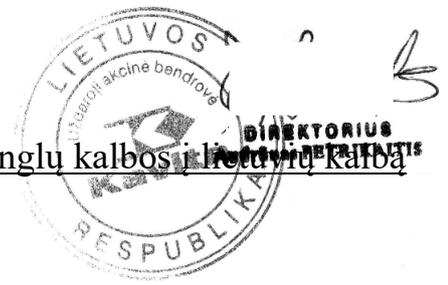
Signature: 

Name: Robin L. Rowe, MSc, RAC
Position: Sr. Director, Regulatory & Medical Affairs

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

| <i>Product code (Cat. No.)</i> | <i>Product Description</i> | <i>GMDN Code</i> |
|--------------------------------|--|------------------|
| 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 |



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 notifikuootojoje įstaigoje:

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

Įgaliotasis atstovas:

Vitreq 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>Product code (Cat. No.)</i> | <i>Product Description</i> | <i>GMDN Code</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 |