

DECLARATION OF CONFORMITY



Manufacturer Bridea Medical bv
Barbara Strozziiaan 101
1083 HN Amsterdam
The Netherlands

Product Gynaecological Speculum, Single-Use

Product codes Orchid Line (all speculum reference numbers)

Classification(s) Class 1, rule 5

Conformity Assessment Route Annex VII

We hereby declare that the above-mentioned medical device, the Speculum, complies with the Medical Device Regulation (EU) 2017/745 (MDR) provisions and all relevant harmonised standards and regulations applicable to class 1 medical devices.
All supporting documentation is retained at the premises of the Manufacturer.

General applicable directive(s) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Certification ISO13485:2016 & EN-ISO13485:2016
MD 725768 BSI

Notified Body BSI Netherlands
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Issued(place/date) Amsterdam, 17 January 2025

Place, date of issue Amsterdam, 17 - 01 - 2025

Signature 

Name Bob Roeloffs
Position Director Bridea Medical bv

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| REF | Description | GTIN |
|----------|---|---------------|
| 1.001.01 | White Orchid Spec - virgo (yellow) | 8720849360029 |
| 1.001.03 | White Orchid Spec - medium (pink) | 8720849360043 |
| 1.001.04 | White Orchid Spec - wide (blue) | 8720849360067 |
| 1.001.05 | White Orchid Spec - long (green) | 8720849360081 |
| 1.001.13 | Orchid Spec SPX - medium (pink) | 8720849360104 |
| 1.001.14 | Orchid Spec SPX - wide (blue) | 8720849360128 |
| 1.001.15 | Orchid Spec SPX - long (green) | 8720849360142 |
| 1.001.21 | Orchid Spec SPX Insert - virgo (yellow) | 8720849361828 |
| 1.001.33 | White Orchid Spec OPEN - medium (pink) | 8720849360166 |
| 1.001.34 | White Orchid Spec OPEN - wide (blue) | 8720849360180 |
| 1.001.43 | Orchid Spec OPEN SPX - medium (pink) | 8720849360203 |
| 1.001.44 | Orchid Spec OPEN SPX - wide (blue) | 8720849360227 |
| 1.006.13 | Orchid Spec SPX - ECO - medium (pink) | 8720849360258 |
| 1.006.14 | Orchid Spec SPX - ECO - wide (blue) | 8720849360265 |
| 1.006.15 | Orchid Spec SPX - ECO - long (green) | 8720849360272 |
| 1.010.01 | White Orchid Spec - ECO - virgo (yellow) | 8720849360289 |
| 1.010.03 | White Orchid Spec - ECO - medium (pink) | 8720849360296 |
| 1.010.04 | White Orchid Spec - ECO - wide (blue) | 8720849360302 |
| 1.010.05 | White Orchid Spec - ECO - long (green) | 8720849360319 |
| 1.011.21 | Orchid Spec SPX Insert - virgo (yellow) | 8720849361798 |
| 1.030.13 | Orchid Spec SPX - ECO - medium (pink) | 8720849360357 |
| 1.030.14 | Orchid Spec SPX - ECO - wide (blue) | 8720849360364 |
| 1.030.15 | Orchid Spec SPX - ECO - long (green) | 8720849360371 |
| 1.031.13 | Orchid Spec SPX - medium (pink) | 8720849360432 |
| 1.031.14 | Orchid Spec SPX - wide (blue) | 8720849360456 |
| 1.031.15 | Orchid Spec SPX - long (green) | 8720849360470 |
| 1.031.33 | White Orchid Spec OPEN - medium (pink) | 8720849360500 |
| 1.031.34 | White Orchid Spec OPEN - wide (blue) | 8720849360524 |
| 1.031.43 | Orchid Spec OPEN SPX - medium (pink) | 8720849360548 |
| 1.031.44 | Orchid Spec OPEN SPX - wide (blue) | 8720849360562 |
| 1.03B.33 | White Orchid Spec OPEN - BULK - medium (pink) | 8720849360388 |
| 1.03B.34 | White Orchid Spec OPEN - BULK - wide (blue) | 8720849360395 |
| 1.03B.43 | Orchid Spec OPEN SPX - BULK - medium (pink) | 8720849360401 |
| 1.03B.44 | Orchid Spec OPEN SPX - BULK - wide (blue) | 8720849360418 |
| 1.040.01 | White Orchid Spec - ECO - virgo (yellow) | 8720849360586 |
| 1.040.03 | White Orchid Spec - ECO - medium (pink) | 8720849360593 |
| 1.040.04 | White Orchid Spec - ECO - wide (blue) | 8720849360609 |
| 1.040.05 | White Orchid Spec - ECO - long (green) | 8720849360616 |
| 1.041.01 | White Orchid Spec - virgo (yellow) | 8720849360654 |
| 1.041.03 | White Orchid Spec - medium (pink) | 8720849360678 |
| 1.041.04 | White Orchid Spec - wide (blue) | 8720849360692 |
| 1.041.05 | White Orchid Spec - long (green) | 8720849360715 |
| 1.16B.13 | Orchid Spec SPX - BULK - medium (pink) | 8720849360913 |
| 1.16B.14 | Orchid Spec SPX - BULK - wide (blue) | 8720849360920 |
| 1.16B.15 | Orchid Spec SPX - BULK - long (green) | 8720849360906 |
| 1.16B.33 | White Orchid Spec OPEN - BULK - medium (pink) | 8720849360890 |
| 1.16B.43 | Orchid Spec OPEN SPX - BULK - medium (pink) | 8720849360883 |

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| 1.181.03 | White Orchid Spec - medium (pink) | 8720849360937 |
| 1.181.04 | White Orchid Spec - wide (blue) | 8720849360944 |
| 1.18B.05 | White Orchid Spec - BULK - long (green) | 8720849360951 |
| 1.200.03 | White Orchid Spec - ECO - medium (pink) | 8720849360968 |
| 1.200.04 | White Orchid Spec - ECO - wide (blue) | 8720849360975 |
| 1.201.01 | White Orchid Spec - virgo (yellow) | 8720849361002 |
| 1.20B.01 | White Orchid Spec - BULK - virgo (yellow) | 8720849361040 |
| 1.20B.03 | White Orchid Spec - BULK - medium (pink) | 8720849361019 |
| 1.20B.04 | White Orchid Spec - BULK - wide (blue) | 8720849361026 |
| 1.220.01 | White Orchid Spec - ECO - virgo (yellow) | 8720849361033 |
| 2.000.03 | Clear Orchid Spec - PARTS - medium (pink) | 8720849361064 |
| 2.001.01 | Clear Orchid Spec - virgo (yellow) | 8720849361071 |
| 2.001.03 | Clear Orchid Spec - medium (pink) | 8720849361088 |
| 2.001.04 | Clear Orchid Spec - wide (blue) | 8720849361095 |
| 2.001.05 | Clear Orchid Spec - long (green) | 8720849361101 |
| 2.001.13 | Orchid Spec SPX - medium (pink) | 8720849361118 |
| 2.001.14 | Orchid Spec SPX - wide (blue) | 8720849361125 |
| 2.001.15 | Orchid Spec SPX - long (green) | 8720849361132 |
| 2.001.33 | Clear Orchid Spec OPEN - medium (pink) | 8720849361149 |
| 2.001.34 | Clear Orchid Spec OPEN - wide (blue) | 8720849361156 |
| 2.001.43 | Orchid Spec OPEN SPX - medium (pink) | 8720849361163 |
| 2.001.44 | Orchid Spec OPEN SPX - wide (blue) | 8720849361170 |
| 2.010.01 | Clear Orchid Spec - ECO - virgo (yellow) | 8720849361194 |
| 2.010.03 | Clear Orchid Spec - ECO - medium (pink) | 8720849361200 |
| 2.010.04 | Clear Orchid Spec - ECO - wide (blue) | 8720849361217 |
| 2.010.05 | Clear Orchid Spec - ECO - long (green) | 8720849361224 |
| 2.031.13 | Orchid Spec SPX - medium (pink) | 8720849361248 |
| 2.031.14 | Orchid Spec SPX - wide (blue) | 8720849361255 |
| 2.031.15 | Orchid Spec SPX - long (green) | 8720849361262 |
| 2.031.33 | Clear Orchid Spec OPEN - medium (pink) | 8720849361279 |
| 2.031.34 | Clear Orchid Spec OPEN - wide (blue) | 8720849361286 |
| 2.031.43 | Orchid Spec OPEN SPX - medium (pink) | 8720849361293 |
| 2.031.44 | Orchid Spec OPEN SPX - wide (blue) | 8720849361309 |
| 2.040.01 | Clear Orchid Spec - ECO - virgo (yellow) | 8720849361316 |
| 2.040.03 | Clear Orchid Spec - ECO - medium (pink) | 8720849361323 |
| 2.040.04 | Clear Orchid Spec - ECO - wide (blue) | 8720849361330 |
| 2.040.05 | Clear Orchid Spec - ECO - long (green) | 8720849361347 |
| 2.041.01 | Clear Orchid Spec - virgo (yellow) | 8720849361385 |
| 2.041.03 | Clear Orchid Spec - medium (pink) | 8720849361392 |
| 2.041.04 | Clear Orchid Spec - wide (blue) | 8720849361408 |
| 2.041.05 | Clear Orchid Spec - long (green) | 8720849361415 |
| 2.041.09 | Clear Orchid Spec - 4 sizes (V, M, W, L) | 8720849361446 |
| 2.181.03 | Clear Orchid Spec - medium (pink) | 8720849361460 |
| 2.181.04 | Clear Orchid Spec - wide (blue) | 8720849361477 |
| 2.200.03 | Clear Orchid Spec - ECO - medium (pink) | 8720849361484 |
| 2.200.04 | Clear Orchid Spec - ECO - wide (blue) | 8720849361491 |
| 2.201.01 | Clear Orchid Spec - virgo (yellow) | 8720849360999 |
| 2.20B.03 | Clear Orchid Spec - BULK - medium (pink) | 8720849361507 |

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| 2.220.01 | Clear Orchid Spec - ECO - virgo (yellow) | 8720849361514 |
| 3.000.03 | White Orchid Spec - BIO - medium (pink) | 8720849361521 |
| 3.001.03 | Orchid Spec - BIO - medium (pink) | 8720849361767 |
| 3.006.69 | Orchid Spec Spoon - BIO - medium & long | 8720849361866 |
| 3.010.03 | White Orchid Spec - BIO - medium (pink) | 8720849361538 |
| 3.010.63 | Orchid Spec Spoon - BIO - medium (pink) | 8720849361835 |
| 3.010.65 | Orchid Spec Spoon - BIO - long (green) | 8720849361842 |
| 3.030.63 | Orchid Spec Spoon - BIO - medium (pink) | 8720849361804 |
| 3.030.65 | Orchid Spec Spoon - BIO - long (green) | 8720849361811 |
| 3.030.69 | Orchid Spec Spoon - BIO - medium & long | 8720849361859 |
| 3.040.03 | White Orchid Spec - BIO - medium (pink) | 8720849361552 |
| 3.041.03 | Orchid Spec - BIO - medium (pink) | 8720849361781 |
| 3.181.03 | Orchid Spec - BIO - medium (pink) | 8720849361774 |
| 3.200.03 | White Orchid Spec - BIO - medium (pink) | 8720849361590 |