

EU DECLARATION OF CONFORMITY

Manufacturer's name: Attain Technologies B.V.
Business address: Van Benthuizenlaan 2
1701 BZ Heerhugowaard
The Netherlands
SRN: NL-MF-000020626

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

In vitro diagnostic medical device(s) covered by this Declaration of Conformity:

See Appendix A.

The devices covered by this EU declaration of conformity are in conformity with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

Common Specifications used and in relation to which conformity is declared:

| CS number | CS Description |
|-----------|----------------|
| None | |

Other Directives / Regulations

No other directives/ regulations applicable to in-vitro diagnostic devices mentioned on this declaration of conformity.

Notified Body involved in the conformity assessment procedure:

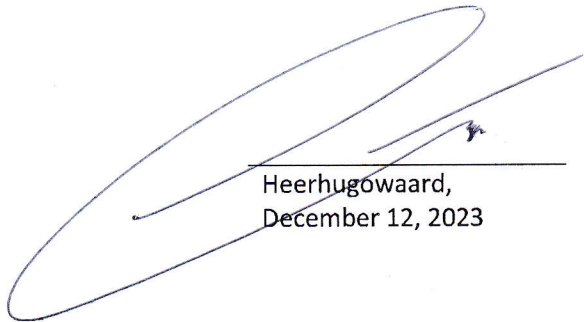
This device is a non-sterile class A device, therefore it is self-declared. No notified body involved in the conformity assessment procedure.

Conformity assessment was performed in accordance with the requirements of *Annex II and III: Conformity assessment based on technical documentation* of the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746. .

QMS certificate: SZ 1381217

Additional information The EU declaration of conformity has a validity period limited by the issue of a revised declaration of conformity.

C.A. Westerveld
CEO



Heerhugowaard,
December 12, 2023

Appendix A: List of In Vitro Diagnostic Medical Device(s) covered by this Declaration of Conformity

| Product Code | Product Name | Basic UDI-DI | Risk Class | Intended Purpose |
|--------------|--|------------------|------------|--|
| CV 1010 2CH | CellVision, 10 micron, 2 chambers horizontal | 0 8720726199 001 | A | The Analysis Slide consist of defined chamber height and is used for assessment of particles in biological liquid (e.g. sperm), it provides an accurate, quick and hygienic,not automated, quantitative analysis of the concentration and motility of particles for microscopic, hematology and fertility use. |
| CV 1010 4CH | CellVision, 10 micron, 4 chambers horizontal | 0 8720726199 025 | A | |
| CV 1010 2CV | CellVision, 10 micron, 2 chambers vertical | 0 8720726199 032 | A | |
| CV 1010 4CV | CellVision, 10 micron, 4 chambers vertical | 0 8720726199 049 | A | |
| CV 1010 6CV | CellVision, 10 micron, 6 chambers vertical | 0 8720726199 056 | A | |
| CV 1012 2CH | CellVision, 12 micron, 2 chambers horizontal | 0 8720726199 063 | A | |
| CV 1012 4CH | CellVision, 12 micron, 4 chambers horizontal | 0 8720726199 070 | A | |
| CV 1012 2CV | CellVision, 12 micron, 2 chambers vertical | 0 8720726199 087 | A | |
| CV 1012 4CV | CellVision, 12 micron, 4 chambers vertical | 0 8720726199 094 | A | |
| CV 1012 6CV | CellVision, 12 micron, 6 chambers vertical | 0 8720726199 100 | A | |
| CV 1016 2CH | CellVision, 16 micron, 2 chambers horizontal | 0 8720726199 117 | A | |
| CV 1016 4CH | CellVision, 16 micron, 4 chambers horizontal | 0 8720726199 124 | A | |
| CV 1016 2CV | CellVision, 16 micron, 2 chambers vertical | 0 8720726199 131 | A | |
| CV 1016 4CV | CellVision, 16 micron, 4 chambers vertical | 0 8720726199 148 | A | |
| CV 1016 6CV | CellVision, 16 micron, 6 chambers vertical | 0 8720726199 155 | A | |
| CV 1020 2CH | CellVision, 20 micron, 2 chamber horizontal | 0 8720726199 162 | A | |
| CV 1020 4CH | CellVision, 20 micron, 4 chambers horizontal | 0 8720726199 179 | A | |
| CV 1020 2CV | CellVision, 20 micron, 2 chambers vertical | 0 8720726199 186 | A | |
| CV 1020 4CV | CellVision, 20 micron, 4 chambers vertical | 0 8720726199 193 | A | |
| CV 1020 6CV | CellVision, 20 micron, 6 chambers vertical | 0 8720726199 209 | A | |
| CV 1030 2CH | CellVision, 30 micron, 2 chambers horizontal | 0 8720726199 216 | A | |
| CV 1030 4CH | CellVision, 30 micron, 4 chambers horizontal | 0 8720726199 223 | A | |
| CV 1030 2CV | CellVision, 30 micron, 2 chambers vertical | 0 8720726199 230 | A | |
| CV 1030 4CV | CellVision, 30 micron, 4 chambers vertical | 0 8720726199 247 | A | |
| CV 1030 6CV | CellVision, 30 micron, 6 chambers vertical | 0 8720726199 254 | A | |

| Product Code | Product Name | Basic UDI-DI | Risk Class | Intended Purpose |
|--------------|---|------------------|------------|--|
| CV 1050 2CH | CellVision, 50 micron, 2 chambers horizontal | 0 8720726199 261 | A | The Analysis Slide consist of defined chamber height and is used for assessment of particles in biological liquid (e.g. sperm), it provides an accurate, quick and hygienic,not automated, quantitative analysis of the concentration and motility of particles for microscopic, hematology and fertility use. |
| CV 1050 4CH | CellVision, 50 micron, 4 chambers horizontal | 0 8720726199 278 | A | |
| CV 1050 2CV | CellVision, 50 micron, 2 chambers vertical | 0 8720726199 285 | A | |
| CV 1050 4CV | CellVision, 50 micron, 4 chambers vertical | 0 8720726199 292 | A | |
| CV 1050 6CV | CellVision, 50 micron, 6 chambers vertical | 0 8720726199 308 | A | |
| CV 1100 2CH | CellVision, 100 micron, 2 chambers horizontal | 0 8720726199 315 | A | |
| CV 1100 4CH | CellVision, 100 micron, 4 chambers horizontal | 0 8720726199 322 | A | |
| CV 1100 2CV | CellVision, 100 micron, 2 chambers vertical | 0 8720726199 339 | A | |
| CV 1100 4CV | CellVision, 100 micron, 4 chambers vertical | 0 8720726199 346 | A | |
| CV 1100 6CV | CellVision, 100 micron, 6 chambers vertical | 0 8720726199 353 | A | |
| CV 1010-102 | CellVision, 10 micron, Sperm Counting Grid (Makler) | 0 8720726199 360 | A | |
| CV 1020-102 | CellVision, 20 micron, Sperm Counting Grid (Makler) | 0 8720726199 377 | A | |
| CV 1020-PV | CellVision, 20 micron, Post Vasectomy Grid | 0 8720726199 384 | A | |
| CV 1100-NI | CellVision, 100 micron, Neubauer improved | 0 8720726199 391 | A | |
| CV 1100-B | CellVision, 100 micron, Bürker | 0 8720726199 407 | A | |
| CV 1100-BT | CellVision, 100 micron, Bürker-Türk | 0 8720726199 414 | A | |
| CV 1100-T | CellVision, 100 micron, Thoma | 0 8720726199 421 | A | |
| CV 1200-FR | CellVision, 200 micron, Fuchs Rosenthal | 0 8720726199 438 | A | |
| BA 1100-NI | Bioanalytic, 100µm, Neubauer improved | 0 8720618711 007 | A | |
| EH 1020-2cv | Exseed, 20µm, 2-chambers vertical | 0 8720618711 014 | A | |
| MES 20-02cv | M.E.S., 20µm, Slides for Vision | 0 8720618711 021 | A | |
| HT 1010-pH | Hamilton Thorne, 10µm, pH strip | 0 8720618711 038 | A | |
| HT 1010-2cv | Hamilton Thorne, 10µm, 2-chambers vertical | 0 8720618711 045 | A | |
| HT 1010-4cv | Hamilton Thorne, 10µm, 4-chambers vertical | 0 8720618711 052 | A | |
| HT 1020-2cv | Hamilton Thorne, 20µm, 2-chambers vertical | 0 8720618711 069 | A | |
| HT 1020-4cv | Hamilton Thorne, 20µm, 4-chambers vertical | 0 8720618711 076 | A | |
| HT 1100-2cv | Hamilton Thorne, 100µm, 2-chambers vertical | 0 8720618711 083 | A | |

| Product Code | Product Name | Basic UDI-DI | Risk Class | Intended Purpose |
|----------------|--|------------------|------------|--|
| OS-B-220 | Ongo Vettech, 20µm, Blue | 0 8720618711 090 | A | The Analysis Slide consist of defined chamber height and is used for assessment of particles in biological liquid (e.g. sperm), it provides an accurate, quick and hygienic,not automated, quantitative analysis of the concentration and motility of particles for microscopic, hematology and fertility use. |
| OS-Y-220 | Ongo Vettech, 20µm, Yellow | 0 8720618711 106 | A | |
| 12050/0220 | Minitube, 20µm, 4-chambers vertical | 0 8720618711 113 | A | |
| 12050/0260 | Minitube, 20µm, 6-chambers vertical | 0 8720618711 120 | A | |
| A.002.045 | Life Optic, 20µm, 4-chambers vertical | 0 8720618711 137 | A | |
| 22467 | Genes Diffusion, 20µm, 4-chambers vertical | 0 8720618711 144 | A | |
| 420 | Spermlide, 20µm, 4-chambers vertical | 0 8720618711 151 | A | |
| 620 | Spermlide, 20µm, 6-chambers vertical | 0 8720618711 168 | A | |
| D4C10 | ISAS, 10µm, 4-chambers horizontal | 0 8720618711 175 | A | |
| D4C16 | ISAS, 16µm, 4-chambers horizontal | 0 8720618711 182 | A | |
| D2C20 | ISAS, 20µm, 2-chambers horizontal | 0 8720618711 199 | A | |
| D4C20 | ISAS, 20µm, 4-chambers horizontal | 0 8720618711 205 | A | |
| D4C20L | ISAS, 20µm, 4-chambers vertical | 0 8720618711 212 | A | |
| Acella 20 | Acella, 20µm, 1-chamber | 0 8720618711 229 | A | |
| Acella 50 | Acella, 50µm, 1-chamber | 0 8720618711 236 | A | |
| Acella 100 | Acella, 100µm, 1-chamber | 0 8720618711 243 | A | |
| Acella 100 SED | Acella, 100µm, 1-chamber SED | 0 8720618711 250 | A | |
| Acella 100 VET | Acella, 100µm, 1-chamber VET | 0 8720618711 267 | A | |
| BB2-C-20 | BIRR, 20µm, 2-chambers vertical | 0 8720618711 274 | A | |
| BB5-C-20 | BIRR, 20µm, 5-chambers vertical | 0 8720618711 281 | A | |
| BB2-C-100 | BIRR, 100µm, 2-chambers vertical | 0 8720618711 298 | A | |
| BB2-G-10 | BIRR, 10µm, Sperm Counting Grid | 0 8720618711 304 | A | |
| BB2-G-20 | BIRR, 20µm, Sperm Counting Grid | 0 8720618711 311 | A | |
| K4 | KUBUS, 20µm, 4-chambers vertical | 0 8720618711 328 | A | |
| K6 | KUBUS, 20µm, 6-chambers vertical | 0 8720618711 335 | A | |
| M5 | Magapor, 20µm, 4-chambers vertical | 0 8720618711 342 | A | |
| M6 | Magapor, 20µm, 5-chambers vertical | 0 8720618711 359 | A | |
| 000401 | Ipransense, 20µm, 4-chambers vertical | 0 8720618711 366 | A | |
| 000403 | Ipransense, 30µm, 4-chambers vertical | 0 8720618711 373 | A | |
| 000402 | Ipransense, 100µm, 4-chambers vertical | 0 8720618711 380 | A | |