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*Document title*
Declaration of Conformity

| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Ulrika Svensson - SEHRBHNU | 2020-11-16 - 13:30 |
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| Released: | QA | Ulrika Svensson - SEHRBHNU | 2020-11-17 - 08:46 |

This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

## The TympoVent Otologic Ventilation Tubes

| REF | Name | Class | GMDN code |
|---|---|---|---|
| 7000 | T-Tube 6,0 mm | IIb | 33794 |
| 7001 | T-Tube 7,5 mm | IIb | 33794 |
| 7002 | T-Tube 12,0 mm | IIb | 33794 |
| 7003 | Straight Tube (OD=2,2 mm) | IIb | 33794 |
| 7010 | Straight Tube (OD=2,7 mm) | IIb | 33794 |
| 7012 | Straight Tube (OD=2,4 mm) | IIb | 33794 |
| 7013 | Bevel Bobbin | IIb | 33794 |
| 7014-W | Reuter Bobbin white | IIb | 33794 |
| 7016 | Collar Button | IIb | 33794 |
| 7017 | Tübingen Type Titanium | IIb | 33794 |
| 7018 | Star Tube 1,0 mm | IIb | 33794 |
| 7020 | Shepard with tail (fluoroplastic) | IIb | 33794 |
| 7021 | Shepard with tail (silicone) | IIb | 33794 |
| 7024 | Reuter Bobbin | IIb | 33794 |
| 7029 | Armstrong Bevel Grommet (silicone) | IIb | 33794 |
| 7030 | Shepard w/o tail (fluoroplastic) | IIb | 33794 |
| 7031 | Donaldson (silicone) | IIb | 33794 |
| 7034 | Armstrong Plain End (silicone) | IIb | 33794 |
| 7037 | Donaldson (fluoroplastic) | IIb | 33794 |
| 7038 | Armstrong Bevel Grommet (fluoroplastic) | IIb | 33794 |
| 7039 | Paparella with tab (ID=1,1 mm) | IIb | 33794 |
| 7043 | Tübingen Type Gold ID=1,25 with wire | IIb | 33794 |
| 7044 | Tübingen Type Gold ID=1,25 without wire | IIb | 33794 |
| 7045 | Tübingen Type Gold ID=1,50 with wire | IIb | 33794 |
| 7046 | Tübingen Type Gold ID=1,50 without wire | IIb | 33794 |

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Each kind of medical device to which the system has been applied complies with the applicable provisions of the Essential Principles and Essential Requirements, the classification rules, applicable standards and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

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*Notified Body:* *Intertek Semko AB, Sweden. Identification no. 0413*
*EC-certificate no. 41310296-04*

*Competent Authority:* *Medical Products Agency, Sweden*

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