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Acid resistant - stainless steel tubes and fittings for medical gases - technical performance and installation

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Purpose
This specification is intended to establish certain requirements regarding tubes and fittings for acid-resistant stainless-steel gas systems for medical gases during purchase, installation and subsequent inspection. The specification complements other applicable documents in the area, such as laws, regulations, documents, directives, guidelines and specifications.

Basic specifications
The tubes and fittings shall comply with the requirements of SS-EN ISO 7396-1: 2016 and SIS HB 370 edition 3.

Purity
The internal surface shall meet the requirement of max 2.5 mg / m^2 hydrocarbon compounds and shall be determined as total surface carbon by the combustion method, which is also the method prescribed in SS-EN 13348:2008. (The combustion method is an advanced and accurate method for analyzing very low levels of organic substances through combustion. Calamo applies the standard with a modified sampling procedure.)

Certificate
The products shall be delivered with a certificate according to EN 10204 3.1, certifying the properties and the internal purity of the material. Compliance with PED 2014/68 / EU and SIS HB 370 edition 3 shall be certified.

Packaging
The tubes should be delivered in tight wooden boxes, each tube / part of tubes shall have a protective package according to the requirements of SIS HB 370 edition 3. Minor deliveries of tubes/fittings can be delivered in cardboard boxes.

Pressure calculation
Calculation of pressure is usually provided by the supplier as guidance. However, the dimensioning of tube systems is also dependent on external forces, thermal stress, static weight, etc. In addition, the construction must be in accordance with local regulations and approved accordingly.

Cleaning methods
Examples of cleaning methods are electropolishing and degreasing.

Material
Tubes and fittings shall be made of acid-resistance austenitic steel.

Welded tubes
Welded tubes shall be manufactured according to EN 10217-7.
The tubes shall be welded from cold or hot rolled strips.
Welding oxides shall be removed.

Common steel grades are EN 1.4404, EN 1.4432 or EN 1.4435.
Alternatively, tubes made according to ASME SA249 are accepted in steel grade
TP 316L if requirements are met for particular material appraisal according to PED 2014/68 / EU.

Tolerances
Up to outer diameter 76.2 mm:
SS-EN ISO 1127 D4 / T3, ASTM A270, A269

Over outer diameter 76.2 mm:
SS-EN ISO 1127 D3 / T3, ASTM A270, A269

The length of the tubes shall be 6 meter nominal.
The tubes shall be prepared for orbital welding.

Seamless tubes
Seamless tubes shall be manufactured according to EN 10216-5.
Common steel grades are EN 1.4404 or EN 1.4435 which also complies with TP316L.

Tolerances
According to SS-EN ISO 1127 D4 / T3, ASTM A270, A269

The length of the tubes shall be 6 meter nominal.
The tubes shall be prepared for orbital welding.

Elbow
Bent from tubes manufactured per above.
After bending, the elbows shall meet the requirement of the pressure vessel directive of at least 14% remaining elongation after cold forming without subsequent heat treatment.
The elbow shall have straight ends and be prepared for orbital welding. (Some, open orbital welding machines can weld bends without straight ends.)

Tolerances: SS-EN ISO 1127 D3 / T3, D2 / T3, ASTM A269

Tees
The tees shall have straight ends prepared for orbital welding and shall be manufactured from tubes manufactured per above. After cold forming and welding of the branch, the tees shall comply with the requirements of the pressure vessel directive of at least 14% remaining elongation after cold forming without subsequent heat treatment.
The welding of the branch should normally be done by orbital welding. The welding shall comply with PED 2014/68 / EU and be performed according to the requirements of SS-EN 1418, SS-EN 288, SS-EN 729, and SS-EN 719. Deviating dimensions may be welded with manual TIG, and in such cases the welding operator shall be qualified according to EN 287-1.

Tolerances: SS-EN ISO 1127 D3 / T3, D2 / T3, D2 / T2, ASTM A269

Reducers / end caps
Reducers and end caps shall have straight ends prepared for orbital welding.
Normally, reducers / end caps are manufactured from bar material according to EN 10272 or ASTM A479.
In some cases, pressed reducers from tubes as above, without straight ends may be used.
Common steel grades are EN 1.4404, EN 1.4435 and ASTM 316L.
Tolerances: SS-EN ISO 1127 D4 / T3, D3 / T3, ASTM A269.

Requirements for installation

General requirements:
The installation shall meet the requirements of SS-EN 13480 Part 1 through 5 and AFS 2016: 1.

Welding method:
Welding should mainly be done with automatic TIG welding (orbital). Only in cases where automatic welding cannot be performed, manual TIG welding is an option.
In the case of orbital welding, operators must be qualified according to SS-EN 1418, welding procedures (WPQR) shall be qualified according to SS-EN ISO 15614-1 and welding data sheets (WPS) shall be manufactured in accordance with SS-EN ISO 15609-1.
For manual TIG, operators shall be qualified according to SS-EN 287-1 / SS-EN-ISO 9606-1, welding procedures (WPQR) shall be qualified according to SS-EN ISO 15614-1 / SS-EN ISO 15613 and welding data sheets WPS) shall be manufactured according to SS-EN-ISO 15609-1.

Validation of welding joints before the start of work:
Because it is difficult to inspect the inside of the welds, it is recommended that each welding operator daily test welds on short pieces with the actual welding machine prior to the start of work, as well as for dimensional change or machine replacement, to ensure that the welding quality meets SS-EN 5817, acceptance limit B. Validation should be documented. See also "Visual inspection after welding" below.

Welding parameters:
Welding parameters for different sizes are calculated and tested in the development of welding procedures and may vary between different fabrics of orbital welding equipment.
All welders should be assigned their own unique ID number to be used in the welding log to identify who performed which welding joints. The welding log should also show the batch / lot number of the components and the used welding parameters.

Welding and protective gas:
As welding gas (same side as the electrode), a gas mixture of 95% Argon and 5% Hydrogen (Varigon H5 *) is recommended.

As protective gas (on the opposite side of the electrode), Argon with minimum purity 99.996% (4.6 *) is recommended.

Maximum impurities in welding gas and protection gas should be max. 5 ppm water and 5 ppm oxygen.

* Linde trade name.

Purity requirements during installation:
- All handling of tubes and fittings where the protective package has been removed should only be done with clean gloves. Tubes and fittings shall be delivered packed so that the ends are protected for contamination. They shall be prepared for installation with orbital welding and have a high surface cleanliness. The requirement of max 2,5 mg / m^2 of hydrocarbons on the inner surface shall be met.

- When the packaging is broken, and the components are exposed to ambient atmosphere or cut / end faced, the cleanliness may quickly deteriorate. It is therefore important not to break the package until installation. All tools and fixtures in contact with the tubes and fittings need to be cleaned properly with isopropyl alcohol or acetone and shall not be used for other materials than stainless/acid resistant steel.
- The ambient atmosphere should be as dust free as practically possible. Grinding, cutting with cutting disks or cutting machining is not permitted to be carried out in the same room where installation is in progress when open fittings/ tube ends are present. All cutting / end facing shall be done dry, with minimum heat and dust / particle generation.
- Because cutting and finishing on site sometimes must be carried out, the welders must check that foreign matter, such as metal chips do not occur inside the tubes or fittings that shall be welded together. In addition, after pre-assembly of the parts to be welded, welders should immediately protect the inside of the tube from foreign matter by sealing with tape. The tape should be chosen so that its adhesive does not damage the inner surface of the tube.

- If the welding operator assesses that it is necessary to clean the joint outside prior to welding, it should be cleaned with a clean cotton wipe which is wetted by a solution consisting of about 20 vol% isopropanol (IPA) or PE Cleaner (Alcoholic solution from Gavatec) in deionized or distilled water.

-Internal surfaces should be cleaned by blowing Argon or Nitrogen to remove loose particles and chips. To completely remove particles from cutting/end facing/deburring from the inside surface, a clean Texwipe Technicloth II or similar should be mounted on a cellular plastic projectile and blown through the tube with Argon or Nitrogen. Warning: At this point, it is very important that the paper covers the entire cell-plastic projectile and that the tube is visually inspected after

the wipe cleaning to ensure that no projectiles or paper remains in the tube.
If the internal surfaces have accidentally been contaminated during installation, these components should be returned to the supplier for cleaning.

Gas flushing prior to welding:
The welding begins at the injection point of the protection gas. Prior to each welding joint, protection gas should be flowed that corresponds to at least 5 times the volume of the between the injection point and the weld joint.
If residual oxygen meters are used, the outgoing protective gas on the opposite side of the injection should contain a maximum of 20 ppm of oxygen before welding. Residual oxygen meters should be used for longer tube distances and connected to an acoustic alarm. Approved residual oxygen content can also be used as a condition (automatic control) to allow the start of the orbital welding machine.

Gas flushing during welding:
The welders shall ensure that protective gas is supplied to the welding point to a sufficient extent. Special protective gas tools may be used if they are kept clean, clean and free from oil and grease.

Gas flushing after welding:
The protective gas flushing shall continue after welding has been completed until the temperature in the heat-affected zone is max. about 100°C.

Visual inspection after welding:
All welding joints shall comply with the requirements of SS-EN 5817, acceptance limit B. The welders shall be able to judge ocular, if the weld complies with SS-EN 5817, see also validation of welding joints above. Endoscope inspection can be used to inspect the weld quality on the inside surface.

Oxides after welding:
By following the gas flushing routine prior to, during and after welding described in this specification, the risk of internal oxidation is minimized. As a guide to assess the approved amount of oxides in the heat affected zone, figure MJ-8.4-2 and figure MJ-8.4-3 in ASME BPE 2016 can be used.
Light buffing of the external surface of the welding joints shall be done with suitable polishing pad that does not contain iron.
Pickling of welding joints with pickling paste can be done as an option, if the requirements for the work environment and the external environment can be met, see safety data sheet for the actual product.

Third-party inspection of welds:
Third party inspection and non-destructive tests may be required according to AFS 2016: 1.
