



EC - Declaration of conformity SAMedical® pipes and fittings

For use in supply systems for compressed medical gases, gases for operating surgical tools and vacuum in medical healthcare facilities.

Amon hereby assures that the pipes and fittings specified in the document; "MDD Product List SMCU" (TF-14.1) and "MDD Product List SMSS" (TF-14.2), 2020-05-26, comply with applicable requirements as in Swedish law 2021:600 – "Lag med kompletterande bestämmelse till EU:s förordning om medicintekniska produkter" and as in the Swedish Medical Products Agency's regulations LVFS 2003: 11 on medical devices. Moreover, all aspects in relation to EN ISO 15001:2010 Anaesthetic and respiratory equipment – Compatibility with oxygen.

The products listed meet the requirements of Medical Device Directive 93/42 EEC 14 June 1993 as amended by 2007/47/EC. Annex I essential requirements and conformity assessment route annex II, excluding section 4.

Product classification is in accordance with MDD – Annex IX, III Classification, Rule 2. Classification is Class IIa, which requires validation by a third party accredited "Notified Body".

The products do not, as far as we know, contain: Pb, Cd, Hg, Cr +6, PBB, PBDE and thus comply with the RoHS directive.

Amon is quality assured and certified by DNV Product Assurance AS with certificate number: 10000347188-PA-NA-NOR with requirements as in EN-ISO 13485: 2016

Requirements for EC Certificate - "Full Quality Assurance System" have been assessed and certified by DNV Product Assurance AS with certificate number: 10000362744-PA-NA-NOR

This declaration applies to products manufactured during the period 2021 to 2023.

Urshult 15 December 2021

A handwritten signature in blue ink, appearing to read "Denis Lodge".

Denis Lodge
Managing Director

Amon AB

address

Industrivagen 8
S-362 54 URSHULT
Sweden

phone

+46 477 205 05
e-post
info@amon.se

www

www.amon.se
Org.nr.
556368-3902