

Declaration – Compliance with ISO 5366:2016 for Tracoe tracheostomy tubes

Herewith, TRACOE medical GmbH, Reichelsheimer Str. 1/3, 55268 Nieder-Olm, declares that all our tracheostomy tubes comply with the requirements from ISO 5366: Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors. This is part of the design verification process, incoming goods inspections and the Essential Requirements according to Directive 93/42/EWG.

ISO 5366 applies for Tracoe twist, silcosoft, mini, and vario tracheostomy tubes.

Nieder-Olm, 1st February 2023

A handwritten signature in blue ink, appearing to read "K. Schrick".

Dr. Katharina Schrick

Head of Regulatory Affairs