

To whom it may concern,

Declaration of conformity

We herewith declare that our products, as listed below, are in conformity with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council ("MDR") which applies to the products.

Manufacturer: Minitube AB

SRN: SE-MF-000002089

Basic UDI-DI: ++B9764000006K

Products: 402604, Tempasept Medimex
402605, Tempasept Medimex with Ointment
403602, Tempasept Minipack Digital
403603, Tempasept Minipack Digital with Ointment
403620, Tempasept Digital

Classification: Class 1, according to Annex VIII in Regulation (EU) 2017/745

This declaration is based on Annex IV in Regulation (EU) 2017/745. Full responsibility for the conformance of these products to the specification is assumed by Minitube.

Trångsviken 2023-01-25

A handwritten signature in blue ink, appearing to be "David Hällgren".

David Hällgren
Vice President
Minitube Medical Products