

OÜ EQUA, reg no. 10255600, Address: Lembitu8, Tartu 50406 Tartu		1(1)
Declaration of Conformity		
Issued in: 16.04.2021	Issued by: Tanel Joost	



## Declaration of Conformity

We, EQUA OÜ, in Lembitu 8, Tartu 50406 / Estonia / SRN EE-MF-000000705 declare under our sole responsibility that following Thermometer covers „Softtemp:

- H71108(UDI-DI) Standard with lubrication
- H71208(UDI-DI) Digital with lubrication
- H71210(UDI-DI) Digital without lubrication
- H71110(UDI-DI) Standard without lubrication

fulfill the requirements of the Regulation (EU) 2017/745 on Medical Devices and that they belong (according to Annex VIII, Rule 5) to the product risk class I and are produced by OÜ EQUA and that above listed products have passed through the conformity procedure which makes it legible to label the product with the CE mark.

This Declaration of Conformity is valid till **16.04.2025** and for all products mentioned above which are produced within this period of time. In case of a change in this product the current declaration becomes invalid.

Softtemp thermometers covers are non-sterile disposable product for covering thermometer to minimise the risk of gross-infection.

Applied standards:

- EVS-EN ISO 14971:2019
- EVS-EN ISO 13485:2016
- EVS-EN ISO 15223-1:2016

16.04.2021, Tartu  
(Date and place)

\_\_\_\_\_  
(signature)  
Tanel Joost  
General Manager  
EQUA OÜ