

DECLARATION OF CONFORMITY

According to Annex III of the Directive 98/79/EC



The signatory who represents the manufacturer below,

AniCon Labor GmbH
Muehlenstraße 13
49685 Hoeltinghausen
Germany

hereby declare that the following products

Product name	Article-No.	Registration-No.
Kylt[®] SARS-CoV-2 Screening RTU	31463 (100 reactions)	DE/CA11/922-4306
	31464 (25 reactions)	
Kylt[®] SARS-CoV-2 Confirmation RTU	31465 (100 reactions)	DE/CA11/922-4307
	31466 (25 reactions)	

are to be classified as “other in-vitro diagnostics” in accordance with Directive 98/79/EC. They conform all the provisions of Directive 98/79/EC that result from this classification.

The conformity assessment procedure for the CE marking was carried out in accordance with Annex III of Directive 98/79/EC. The manufacturer keeps the technical documentation about the relevant provisions.

Hoeltinghausen, 5th May 2020

M. Liman, PhD
Managing Director
AniCon Labor GmbH