To whom it may concern,

We confirm that all BioeXsen Real Time PCR kit based on nucleic acid amplification technology (NAT) have a quality management system to maintain the required quality, safety and performance in the use of state-of-the-art and in vitro diagnostic medical devices and to ensure the reliability of the results obtained. All BioeXsen Real Time PCR kit are IVD-CE certified (European In Vitro Diagnostic Medical Device Directive 98/79/EEC).

We hereby confirm that our product (BioeXsen SARS-CoV-2 Triple Gene RT-qPCR Kit) can be used as point of care device with following condition. When;

- vNAT® Buffer and vNAT® Transfer Tube as extraction solution method used for respiratory specimens
- CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad), QuantStudio™ 5, 0.1 mL/QuantStudio™ 5 Dx, 0.1 mL (Applied Biosystems™), and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) Real-Time PCR Detection systems are used as test instrument.
- FastFinder software (online) is used for result evaluation, interpretation, and reporting
- used by person trained about application of the "BioeXsen SARS-CoV-2 Triple Gene RT-qPCR Kit" by BioeXsen application specialists.

The use of our products by lay person is strictly prohibited.

BioeXsen GmbH

BioeXsen
HEALTH TECHNOLOGY

Klaus Skripalle

Managing Director