



To whom it may concern

PRODUCT STATEMENT

We, SOCOREX ISBA SA, herewith declare that the sterilization pouches

**Qualitix® 3210.XXXX,
All lot numbers**

are manufactured under controlled conditions in accordance with ISO 9001 and ISO 13485 standards.

These products are not supplied in sterile condition.
Correct processing and resulting sterility are the responsibility of the user.

SOCOREX ISBA S.A.

A handwritten signature in blue ink, appearing to read "H. Ammann", written over a horizontal line.

Jean-Marc Ammann
Quality System & Regulatory Affairs Manager

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SOCOREX ISBA SA

Ecublens, December 24th, 2021

