



Knick
Elektronische Messgeräte
GmbH & Co. KG
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Manufacturer's Declaration

Document No.

SC260603D

Subject

**Manufacturer's Declaration on the Cytotoxicity
of the Sensors of the SE558X/*-N* Series**

Confirmation

Knick confirms that sensors of series
SE558X/*-N*
no leachable substances release in cytotoxic concentrations.

The cytotoxic effects of the sensor type were investigated. The decrease in mitochondrial dehydrogenase activity was used as a measure of cytotoxicity. Cell growth was analyzed using XTT staining, and the results were evaluated using an extract from the SE558 sensor. In addition, a grading score analysis was conducted.

According to the expert opinion, in vitro screening is recommended for assessing cytotoxic potential, both when evaluating new materials or formulations for potential use in medical applications and as part of a quality control program for established medical materials and medical devices.

Six concentrations of the test extract (44.4 %, 29.6 %, 10 %, 1 %, 0.7 %, 0.35 %) were tested. Biological reactivity (cell degeneration and malformation) was evaluated in accordance with USP-NF 2026, Issue 1, Chapter <87>.

For the highest concentration of the sensor extract, the effect was rated as Grade 1; for all other concentrations, it was rated as Grade 0.

When used for its intended use, the sensor does not have any cytotoxic effects.

Berlin, June 03, 2026

Knick Elektronische Messgeräte GmbH & Co. KG

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