Manufacturer´s Declaration

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Document No.	**TX250321B**
Subject	**Manufacturer's Declaration on the cytotoxicity of the sensors of the SE555X/*-NMSN* and SE555X/*-AMSN* series**
Confirmation	Knick confirms that for sensors of series SE555X/*-NMSN* SE555X/*-AMSN* the gel Rheolid is used for the reference system. Based upon this intended use, and in accordance with the DIN EN ISO 10993-1: 2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" – the biological risk of cytotoxicity was evaluated under conditions of industrial use. The potential of cytotoxicity of the aforementioned test material was investigated by the using the evaluation test method in accordance with DIN EN ISO 10993-5: 2009 "Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity" and USP <87>: "Biological reactivity tests, in vitro" (final report 15677651 1.1). The applied extract concentrations of 0.69 % (dilution of 1:144) and 0.35 % (dilution of 1:288) of the "Electrolyte gel Rheolid" showed cell viability ≥90 % which is considered to have no cytotoxic potential. According to the manufacturer, the extract concentration of 0.69 % (dilution of 1:144) is identified as the worst case for industrial use of the tested chemical "Electrolyte gel Rheolid". The worst case is defined as the complete depletion of the "Electrolyte Gel Rheolid" contained in the pH sensor into the contents of a bioreactor of the size used in the pharmaceutical industry. Based on the study results obtained and considering the provisions of the harmonized standard DIN EN ISO 10993-1, it is concluded that the intended use of "Electrolyte gel Rheolid" does not cause cytotoxic effects in its industrial application environment.

Berlin, March 21, 2025

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