DECLARATION OF CONFORMITY

Cytotoxicity Testing of Process Electrodes ”SE571”

Manufacturer:

Knick Elektronische Messgeräte GmbH & Co. KG

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Scientific Background and Regulatory Requirements

The process electrodes of the product line ”SE571” are electrodes for measuring pH, temperature and/or redox potentials in bioreactors in the pharmaceutical industry. The reference system with the PTFE diaphragm is for all products identical and is filled with “Rheolid”, a KCl saturated Polyacrylamid gel.

Based upon this intended use and in accordance with ISO 10993-1: 2009 "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management system” the biological risk of cytotoxicity was evaluated under conditions of industrial use.

Assessment

Cytotoxicity

The potential of cytotoxicity of the KCl saturated Polyacrylamid gel was investigated within the cytotoxicity test (growth inhibition test in L929 mouse fibroblasts using an elution test) in accordance with ISO 10993-5:2009 and USP 31, 2008, Chapter <87> (mdt final report 10z055).

Following dilutions of the viscous test material were examined: 1:36, 1:72, 1:144, 1:288 which exhibited growth inhibitions between 100 % and 15 %. However, the applied extract concentrations of 0.69 % (dilution of 1:144) and 0.35 % (dilution of 1:288) of the electrolyte gel “Rheolid” showed no cytotoxic reaction.

Additionally, the cytotoxic effects of the electrode materials, coming in direct contact with the process materials, were additionally investigated within the cytotoxicity test (growth inhibition test in L929 mouse fibroblasts using an elution test) in accordance with ISO 10993-5:2009 and USP 39, 2016, Chapter <87> (UL MDT final report 11278916 1.1). As the process electrodes within the product line ”SE571” contains several materials, the investigation was performed with the process electrode tip SE571X/1-AVPN.

None of the extract concentrations of the electrode showed any cytotoxic reaction.

Conclusion

According to the provision of the manufacturer the extract concentration of 0.69 % (dilution of 1:144) of the electrolyte gel “Rheolid” is identified to be the worst case situation in the industrial use. The worst case is defined as a complete depletion of the electrolyte gel available in process electrodes within the product line ”SE571” into the content of a bioreactor of respective size utilized in the pharmaceutical industry. Furthermore, no cytotoxic reaction was observed for the electrode tip materials.

Based upon the study results obtained, and considering the provisions of the harmonised standard ISO 10993-1 it is concluded that the intended use of the process electrodes within the product line ”SE571” (list of all process electrodes are listen in the attachment of this document) causes no cytotoxic effects in its industrial application environment.

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Attachment: Overview of the process electrodes within the product line ”SE571”

The above Declaration of Conformity is valid for the following products:

SE571X/Y XXXX type of sensor

Explanation of code:

SE571X/ Y- X XX X

Y-		1 to 4; length of sensor (120mm to 425mm)
	N	without solution ground
	A	with solution ground
	MS	Memosens connector
	VP	VP connector
		N pH glass low impedance
		H pH glass high impedance