

TEST REPORT

Test requested: ***In vitro* cytotoxicity test (as per ISO 10993-5)**
Direct contact

Test material:

Number of test materials: 2
Nature of test material: Plastic
Test material code: TM1
TM2

Study dates:

Test material received: 18 July, 2016
Begin of testing: 19 July, 2016
End of testing: 21 July, 2016
Final report: 21 July, 2016

Cell line: L929 mouse fibroblast NCTC clone 929 strain L

Controls:

Negative control: High density polyethylene
Positive control: Organotin stabilized polyurethane

Test method:

Preparation of materials and controls: The test materials, negative and positive controls were prepared in accordance with ISO 10993-12
Test procedure: The test was carried out as per ISO 10993-5

Results:

Table 1- Reactivity grades for direct contact test

	Reactivity grades as defined below
TM 1	0
TM 2	4
Negative control	0
Positive control	4

Description of reactivity zone

0 = No reactivity No detectable zone around or under specimen
1 = Slight reactivity Some malformed or degenerated cells under specimen
2 = Mild reactivity Zone limited to area under specimen
3 = Moderate reactivity Zone extending specimen size up to 1 cm
4 = Severe reactivity Zone extending farther than 1 cm beyond specimen

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Table 2- Quantitative measurements of cytotoxic effects by MTT assay

	Mean value of optical density at 570nm	Viability %
TM 1	0.687	87
TM 2	0.327	24
Negative control	0.786	100
Positive control	0.219	6
Blank	0.179	

$$\text{Viability \%} = 100 \times \text{OD}_{570t} / \text{OD}_{570c}$$

where

OD_{570t} is the mean value of measured optical density of the test material after subtracting blank (medium control)

OD_{570c} is the mean value of measured optical density of the negative control after subtracting blank (medium control)

References:

ISO 10993-5, 2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-1, 2003, Biological evaluation of medical devices - Part 1: Evaluation and testing

ISO 10993-12, 2008, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials