

CERTIFICATE OF COMPLIANCE

BSL BIOSERVICE

Scientific Laboratories GmbH Behringstr. 6/8 82152 Planegg Germany

Phone +49 (0)89 899 650-0 Fax +49 (0)89 899 650-11

Testmaterial:

EPDM 70 PEROXIDE CURED M534

Supplier:

DUCI SRL

Via Monte Avaro, 69 24060 Chiuduno (BG)

Italy

Study

performed:

The following study was performed in order to determine the biocompatibility of the test item according to USP <87> "Biological Reactivity Tests, *in vitro* - Elution Test", ISO 10993-1: 2009, "Evaluation and testing within a risk management process", ISO 10993-5: 2009, "Tests for *in vitro* cytotoxicity" and ISO 10993-12: 2007, "Sample preparation and reference materials".

CYTOTOXICITY (BSL Project No. 123390)

Results:

No leachable substances were released in cytotoxic concentrations from the test item. Hence, the test item meets the criteria of the USP as well as the ISO test for evalutation of cytotoxicity *in vitro*.

BSL BIOSERVICE Scientific Laboratories GmbH
Behringstraße 6/8
D-82152 Planegg
Germany

Dr. Benjamin Hoy

Biological Safety Testing

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