
BIOCOMPATIBILITY CERTIFICATE

TEST MATERIAL(S): **HYDROPHOBIC COATING FROM P2I**

SUPPLIER: **P2I LIMITED**

RAW MATERIAL: **VAPOUR, 1H,1H,2H,2H-PERFLUORODECYL ACRYLATE**
(CAS 27905-45-9)

OEM MANUFACTURER: **APOLLO SCIENTIFIC LTD**

TESTS: **THE ABOVE MENTIONED MATERIAL(S) IS TESTED,**
USING SATURATED TEST PLATES, FOR
BIOCOMPATIBILITY ACCORDING TO ISO 10993 AND
FDA BLUE BOOK MEMORANDUM G95-1. TEST REPORTS
ARE AVAILABLE ON REQUEST. THE FOLLOWING
STUDIES HAVE BEEN PERFORMED,
- CYTOTOXICITY
- SENSITIZATION
- IRRITATION/INTRACUTANEOUS

RESULT: **THE TESTS MATERIAL(S) SHOWS NO RELEVANT**
BIOLOGICAL EFFECTS IN THE STUDIES CARRIED OUT

Based on the above mentioned information, we hereby confirm that the above mentioned material(s) are suitable for use in manufacturing of medical device for skin contact applications.

GN ReSound A/S



Lars Hagander
Vice President
Corporate Quality