



CERTIFICATE OF CONFORMITY

Certificate for Lot Number: 43379

Product Code: TS/5-17 Product: PROBACT Clear, Polystyrene/Viscose (Pack Size 100)

Date Of Manufacture: 11/2013 Expiry: 2015-12 Shelf Life: 24 months

This is to certify that the product detailed on this certificate conforms to Technical Service Consultants Ltd procedures and specifications and has performed the tests detailed below within documented parameters.

Sterilisation Reference, Isotron PLC Number

S11083637-1-1 - 645937 : Dose 28.3 - 43.4 kGy, S11086716-1-1 - 662067 : Dose 28.8 - 43.6 kGy,
S11089950-1-1 - 683352 : Dose 26 - 41.3 kGy

For Irradiated products batch release is controlled by the verification of the radiation dose throughout the load.

Autoclave Reference, Time Manufactured

For autoclaved products, either a temperature datalogger or visual sterilisation indicator are used to confirm that sterility was achieved.

Physical and Microbiological Assurance

Tests Performed	Results Obtained
Batch Release (Sterility)	Pass
Validation of transport media according to M40-A	Pass
Recovery of Indicator organism <i>P. aeruginosa</i> ATCC BAA-427	Pass
Recovery of Indicator organism <i>N. gonorrhoeae</i> ATCC 43069	Pass
Recovery of Indicator organism <i>B. fragilis</i> ATCC 25285	Pass

Overall Result: Pass

Certificate Issued by: Joanne Walsh Certificate authorised on 03.01.2014

Electronically generated on 3rd January 2014 - valid without signature

Sent to vickie (vickie.bruckshaw@tscswabs.co.uk)