CE 1984

LEUKOCYTE FILTER CERTIFICATE OF ANALYSIS

PRODUCT NAME : KAN. BC POOLING PLT- FILT 5D STR

CODE NO : 20004146520

LOT NUMBER : K002212107

QUANTITY RELEASED : 300

RELEASE DATE : 02.01.2023

PRODUCTION DATE (Y-M) : 2022-12

EXPIRY DATE (Y-M) : 2025-12

TYPE OF STERILIZATION : GAMA IRRADIATION

STERILIZATION DATE : 28.12.2022

Filter information

Code	Description	Raw material	Filter type
58559	Sepacell filter PLX-5	PC+PET	Hard

Control and Tests	Reference	Acceptable Limits	Results
Physical Tests	ISO 3826-1:2013 + Internal Methods	Must be within the limits indicated for each test	PASS
Leakage controls	ISO 3826-1:2013 + Internal Methods	No leakage is allowed on visual inspection	PASS
Tensile strength of line connectors	ISO 3826-1:2013	Must resist a pull force of 15 N for 15 s.	PASS
Pyrogenicity test (1)	EP 2.6.14 2010:20614 Method A	Must be apyrogen	APYROGEN
Sterility test (1)	EP 2.6.1 04/2011:20601	Must be sterile	STERILE
Bioburden (2)	ISO 11737-1	10 cfu / 40 mL	PASS

(1) Controls which are performed during stability studies

(2) Controls which are performed monthly

Quality Control Assistant Manager (Name, Signature) : S.YAVUZ

We hereby declare that the above mentioned products meet all applicable provisions of Council Directive 93/42/EEC and all applicable harmonised and international standards for medical devices. All supporting documents are retained under the premises of the manufacturer.