

DRAFT AMENDMENT NO. 1 MAY 2024

TO

IS 758 : 2023 MEDICAL TEXTILES — ABSORBENT COTTON GAUZE —
SPECIFICATION
(Fifth Revision)

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(Page 1, clause 4.2) — Insert the following new clause after 4.2 :-

‘4.3 Cleanliness–Microbial/ Bioburden Test

The cotton gauze shall confirm the requirement of cleanliness–microbial/ bioburden for sterile and non-sterile product. For sterile product, ‘no viable microorganism shall be present’ and for non-sterile product, it shall be ≤ 300 (CFU/100 cm²) when tested in accordance with ISO 11737 (Part 1).’

[(Page 2, Table 1, Sl No (ix), col 4)] — Substitute ‘Viewing under ultraviolet light at 365 nm’ for ‘Viewing under ultraviolet light.’

[(Page 2, Table 1, Sl No (x)] — Delete.

(Page 4, clause 2, Annex A) — Substitute ‘ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products’ for ‘IS 10150 : 1981 Guide for sterilization of medical products.’