

भारतीय मानक ब्यूरो /BUREAU OF INDIAN STANDARDS
(पूर्वी क्षेत्रीय प्रयोगशाला)/Eastern Regional Laboratory

हमारा संदर्भ/Our Ref: ERL/MICRO/13422

DATE:- 12.11.2024

विषय / Subject: Comment regarding addition of test method in Cl. 7.4 Sterility

इस संबंध में प्रस्तावित बदलाव(ओं) पर विचार करने के लिए एफ.ए.डी द्वारा निम्नलिखित टिप्पणियों पर ध्यान दिया जाए:

Sl. No	IS	Standard	प्रस्तावित बदलाव/ Proposed change	वजह/Justification
1	IS 13422: 2024 / ISO 10282: 2023	Single-Use Sterile Rubber Surgical Gloves — Specification	Clause 7.4 Sterility 7.4.1 Gloves shall be sterilized. The nature of the sterilization process shall be disclosed on request. 7.4.2 Gloves when tested in accordance with IS/ISO 11737-1: 2018, the Total Microbial count (Total number of bacteria and fungi) (CFU /100 cm ²) shall be Absent.	The Clause 7.4 of IS 13422:2024 / ISO 10282:2023 explicitly does not specify any test method for checking the sterility of gloves which in our opinion is an essential requirement, the product being a sterile one. Similar requirement exist for IS 3319: 1995 BLADES, SURGICAL, DETACHABLE (BARD PARKER TYPE) AND HANDLES — where each batch of the sterilized blades shall meet the requirements of sterility, when tested in accordance with IS 10150: 1981.” [IS 10150: 1981 has been superseded by IS/ISO 11737-1: 2018].

OIC(Micro)

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RSh
12/11/2024
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cTP (Microbiology)