Email **MHD BIS**

REVISION IN IS:15354 TO GIVE MORE PROTECTION AND LESS COST.

From : ho@kanamlatex.com Fri, May 12, 2023 02:07 PM

Subject : REVISION IN IS:15354 TO GIVE MORE PROTECTION AND LESS COST.

To : BUREAU of INDIAN STANDARDS <no-reply@bis.gov.in>

Cc : MHD BIS <mhd@bis.org.in>, donaldsk@kanamlatex.com, mariappans@kanamlatex.com, PRIYANKA Mehra <priyankamehra@bis.gov.in>

KL/G-11.

Dear Mr.Harshada Ganesh Kadam,

Sub: **REVISION IN IS:15354 TO GIVE MORE PROTECTION AND LESS COST.**

We are in receipt of your mail dated 11th May 2023 and glad to note that you will be holding TECH Committee meeting on 15th May.

As we come for the Medical Glove industry, we would like to offer our view on BIS specification for medical examination gloves - IS:15354.

IS:15354, pays more attention to glove thickness and less importance to barrier properties like pin holes. The primary intended use of medical examination glove is to prevent cross contamination between healthcare worker and patient. Hence shouldn't IS:15354 pay more attention to pinholes and follow what EN 455-1,2,3,4 has (**AQL 1.5** as gainst **AQL 2.5** which is very relaxed allowance).

IS:15354 asks for minimum thickness of gloves to be 0.08mm. at palm and finger and goes on to specify that if the glove is textured the thickness should be increased to 0.11mm. i.e. plus 0.03 mm. This is very arbitry as textures vary from mild to very high texture. Thickness is important to the extend that the glove should not tear, while donning. To prevent manufacturer from making very thin glove, EN specifies, that **force at breack using 3mm. dumbell cut piece should be 6 Newton**. Manufacturers have been able to offer Nitrile Gloves with average weight in size medium of 3.5 g. to meet this required physcial properties and AQL of 1.5 for pinholes. In case of latex examination gloves, the minimum weight that will be required to meet force at break of 6 newton will be around 5g. (size Medium).

Basically the specification should look at intended use, how long is the product used, and cost of the product. Normally a medical exam glove is used for very short time - may be one minute to 5 minutes or at most 10 minutes as GMP, asks that a medical practitioner should not use gloves to handle more than one patient.

BIS 15354 increases the cost of product, by asking minimum thickness of 0.11mm. when it is not needed and reduces the safety by allowing higher AQL for barrier properties to AQL 2.5 which is a paradox. This to our opinion is wrong, especially for medical examination gloves made from

synthetic latex like Nitrile, Neoprene etc. Have users of medical examination gloves (Hospitals/Labs/Dentists been consulted). Do they prefer a thicker glove (more cost) but with AQL of 2.5 for pinholes or would they prefer a slightly thinner glove (3.5g. as against 4.5g.) and with less tolerance to barrier properties like maximum allowed pinholes of 1.5

National and International standards fix the **minimum** requirements. If a user wants a thicker glove as per his intended use, he will ask for 4.5g. or 5 g. or 5.5.g. or even 7 g. (as in case of high risk gloves) and he will be willing to pay more.

Do hope BIS will re-consider IS:15354, and align it will present intended use and takes into account, higher degree of safety (reduce pinholes) and less cost, reduce consumption of raw materials and chemicals used - (nitrile latex).

To prevent gloves being too thin, force at break of 6 (N) will taken care of it. Also number of pieces in a dispenser box should be 100 pcs. +/- 2 pcs. based on weight. It is not practical to count and pack 100 pcs. or 200 pcs. to an inner box. Todays machines produce more than 40,000 pcs. per hour.

The average import of Nitrile & Latex Exam Glove is 35.42 crores per month.

Regds,

Ravi Abraham
(Mg. Director)
KANAM LATEX INDUS.PVT.LTD.
Kottayam, Kerala
India.

cc to: Mr.Donald/Mr.Mariappan.

ra/ba.

-------- Forwarded Message --------

Subject: Meeting Notice: 10th meeting of Hospital Equipment and Surgical Disposal Sectional Committee on 15-5-2023 at 11:00

Date: Thu, 11 May 2023 15:37:33 +0530

From: BIS <no-reply@bis.gov.in>

Reply-To: BIS <no-reply@bis.gov.in>

To: ho@kanamlatex.com

MEETING NOTICE

(Physical and Virtual meeting)

Reference: **Date:11-May-2023**