

**Email****MHDtcTWELVE Medical Equipment Department**

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**DELETING IS:4148 FOR RE-USE OF SURGICAL GLOVES**

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**From :** ho@kanamlatex.com

Wed, May 22, 2024 01:46 PM

**Subject :** DELETING IS:4148 FOR RE-USE OF SURGICAL GLOVES 2 attachments**To :** MHDtcTWELVE Medical Equipment Department  
<mhd12@bis.gov.in>**Cc :** PRIYANKA Mehra <priyankamehra@bis.gov.in>,  
Head MHD BIS <hmhd@bis.gov.in>,  
sunilkant61@gmail.com,  
forumcoordinator@aimedindia.com,  
acj@kanamlatex.com, donaldsk@kanamlatex.com

KL/G-11.

Dear Ms.Harshada Kadam,

Sub: **DELETING IS:4148 FOR RE-USE OF SURGICAL GLOVES**

Please refer to the various representations we have made to B.I.S with regard to subject cited above as No One in the World would have a product standard for Non-Sterile Re-usable Surgical Gloves, which has to autoclaved and sterilized prior to use, and then re-used 5 times.

The last we heard on the subject was that BIS, will contact users and then revert back and take a decision.

We have tried to contact many buyers of Non-Sterile Surgical Gloves, but no one autoclaves and sterilize after use, and wash a used glove and re-use it.

Has BIS been able to find any re-users of non-sterile surgical gloves??

How can CDSCO also give Licence to any manufacturer to make re-usable surgical glove as it will not comply with essential principals and also comply with ISO:13485.

We do hope this Old Standard will finally be buried or amended so that non-sterile surgical glove will be available for use in Wards and not for **Surgery.**

Our mail written to you on 24.8.2023 along with copy of mail written to Mr.Mathew in 2022 is also enclosed.

Please acknowledge receipt.

Regds,

Ravi Abraham  
(Mg.Director)

Encls: Mail to Mr.P.Mathew and His reply.

cc to: Mr.Rajiv Nath, AIMED.  
cc to: Mr.Donald  
cc to: Mr.Abraham C. Jacob  
ra/ba.

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

**Subject:**IS:4148 - RE-USABLE SURGICAL GLOVES IS OUT DATE

**Date:**Thu, 24 Aug 2023 14:05:28 +0530

**From:**Kanam Latex Ind Pvt Ltd <[ho@kanamlatex.com](mailto:ho@kanamlatex.com)>

**To:**[mhd12@bis.gov.in](mailto:mhd12@bis.gov.in)

**CC:**PRIYANKA Mehra <[priyankamehra@bis.gov.in](mailto:priyankamehra@bis.gov.in)>, Head MHD BIS  
<[hmhd@bis.gov.in](mailto:hmhd@bis.gov.in)>, [sunilkant61@gmail.com](mailto:sunilkant61@gmail.com), forumcoordinator  
<[forumcoordinator@aimedindia.com](mailto:forumcoordinator@aimedindia.com)>

KL/G-011.

Dear Ms. Harshada Kadam,

Sub: **IS:4148 - RE-USABLE SURGICAL GLOVES IS OUT DATE.**

We have been writing to BIS, for sometime now with regard to **validity** of present IS:4148, which is for Non-Sterile Re-usable Surgical Gloves - which requires hospitals to Sterilize the same use it and re-use it, for 5 Surgical procedures - as it's intended use. Even CDSCO, does not recognize the concept of re-usable surgical gloves and they do not give manufacturing licence for Re-usable Surgical Gloves, with autoclave sterilization at hospital prior to use. This means:

- 1) Hospital purchases Non-Sterile Surgical Gloves.
- 2) It then autoclaves, sterilizes it and gives the product **packed in cloth** to the O.T.
- 3) O.T Staff and Surgeons use the gloves and then take it off and keep the used gloves and it is sent for **wash**.
- 4) The blood stained gloves are washed and **dried (usually hang to dry)** then powdered and again autoclaved sterilized, and used.

No one will know if the surgical glove had a **puncture** or if it's **film has lost it's barrier properties** and since the product is autoclaved sterilized without following a

validated sterilization process, no one can assure that the glove is **Sterile**.

How do we still have a BIS Standard for Non-Sterile Surgical Gloves to be re-used in 2023. We just sent a space craft to the Moon.

We can have a standard for Non-Sterile Surgical Gloves for use in Wards and in ICU etc., and this is still what many hospitals still do.

Please find enclosed:

1) Our Mail dated 15th July 2022 addressed to Mr.P.Mathew (Exhibit - I).

2) Reply from Mr. P.V.Mathew dated 15/07/2022. (Exhibit II)

However, so far nothing has happened in re-validating IS:4148 and we pray that this standard is taken up without any further delay. We may be the only Country in the World that still has a National Standard for Re-usable Surgical Gloves.

This standard also has a clause for PH of gloves to be  $7 \pm 1$ . This was made when glove manufacturing was a manual process and in this process, manufacturers manually dipped moulds into acid tank and then dipped the acid coated mould into latex to coagulate the film and then further processed it. But today's process is totally different, and PH of glove is more Alkaline and hence no standard asks for gloves PH to be  $7 \pm 1$ . Why more Alkaline, because the coagulant is Alkaline and no longer Acidic.

Please do acknowledge receipt of this mail and do hope it will be taken up urgently with BIS MHD-12.

Regds,

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

cc to: Lt.Gen.Sunil Kant(Chairperson)  
cc to: Mr.Priyanka Mehra  
cc to: Mr.Rajiv Nath, AIMED.  
ra/ba.

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