*भारतीय मानक*

**स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण**

**भाग 3 लियोफिलाइजेशन**

*Indian Standard*

**Aseptic Processing of Health Care Products**

**Part 3 Lyophilization**

ICS 11.080.01

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 3) which is identical to ISO 13408-3:2006, ‘Aseptic processing of health care products — Part 3: Lyophilization’ issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposable Products Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard

without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

1. Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’
2. Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian

Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

|  |  |  |
| --- | --- | --- |
| *International Standard* | *Corresponding Indian Standard* | *Degree of**Equivalence* |
| ISO 9001, Quality management systems — Requirements | IS/ISO 9001 : 2015, Quality Management Systems — Requirements (*Fourth Revision*) | Identical |
| ISO 13408-4, Aseptic processing of health care products — Part 4: Clean-in-place technologies | MHD/12/25436, Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies | Identical |
| ISO 13408-5, Aseptic processing of health care products — Part 5: Sterilization in place | MHD/12/25437, Aseptic Processing of Health Care Products Part 5 Sterilization in Place | Identical |

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

|  |  |
| --- | --- |
| *International Standard* | *Title* |
| ISO 13408-1 | Aseptic processing of health care products — Part 1: General requirements |