Master Standards List (SCN048426)

| **Standard Type** | **Standard Number** | **Standard Title** |
| --- | --- | --- |
| Regulation International | ISPM No. 15 (May 29, 2019) | Regulation of wood packaging material in international trade |
| Regulation EU | EU 94/62/EC | European Packaging and Waste Directive European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste |
| Ext Std-Russia | GOST R ISO 10993-1-2021  ISO 10993-1:2018 (IDT) | Medical devices. Evaluation of the biological effect of medical devices. Part 1. Evaluation and research in risk management |
| Ext Std-Russia | GOST ISO 11607-1-2018  (ISO 11607-1:2006, including Amd 1:2014) (IDT) | Packaging for terminally sterilized medical devices. Part 1. Requirements for materials, sterile barrier systems and packaging systems |
| Ext Std International (ex-ISO, IEC) | ISO/TS 16775:2021 | * Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2 - Second edition |
| Ext Std International (ex-ISO, IEC) | EN 13429:2004 | Packaging Reuse |
| Ext Std International (ex-ISO, IEC) | ISO 11607- 1:2019  EN ISO 11607-1:2020 A11 2022 | [Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Second Edition](https://ewb.ihs.com/#/document/RLYXGGAAAAAAAAAA?pr=wl&ewb-token=KGTlatpHW5iI8gGKi38N2XrtoM0V8uZ%2BKH7OlLphHPRHeKv9StI5IAFv%2FoThU9G9AoDHJDoaSmouThtiSonvBqELTDrRFNy7kob7GRkToGtJ9qXcASqP0c%2FxLfwdkU%2FjvChLTwcwqyzKN71HYc0NxsTaJZb%2BhPZf9ouRsvmfHSo%3D) |
| Ext Std International (ex-ISO, IEC) | ISO 11607- 2:2019  EN ISO 11607-2:2020 A11 2022 | [Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Second Edition](https://ewb.ihs.com/#/document/GMYXGGAAAAAAAAAA?pr=wl&ewb-token=KGTlatpHW5iI8gGKi38N2XrtoM0V8uZ%2BKH7OlLphHPRHeKv9StI5IAFv%2FoThU9G9AoDHJDoaSmouThtiSonvBqELTDrRFNy7kob7GRkToGtJ9qXcASqP0c%2FxLfwdkU%2FjvChLTwcwqyzKN71HYc0NxsTaJZb%2BhPZf9ouRsvmfHSo%3D) |
| Ext Std International (ex-ISO, IEC) | EN 13428:2004 | Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction |
| Ext Std International (ex-ISO, IEC) | EN 13427:2004 | Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste |
| Ext Std International (ex-ISO, IEC) | EN 13432:2000 / AC:2005 | Packaging - Requirements for Packaging Recoverable Through Composting and Biodegradation - Test Scheme and Evaluation Criteria for the Final Acceptance of Packaging - CORR 17016: May 31, 2007 |
| Ext Std International (ex-ISO, IEC) | EN 13431:2004 | Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value |
| Ext Std International (ex-ISO, IEC) | EN 13430:2004 | Packaging - Requirements for packaging recoverable by material recycling |
| Ext Std International (ex-ISO, IEC) | EN ISO 780:2015 ISO 780:2015 (EQV) | Packaging - Distribution packaging - Graphical symbols for handling and storage of packages (ISO 780:2015) |
| Ext Std ASTM | ASTM D6653/D6653M-13 (R2021) | Standard Test Methods for determining the Effects of High Altitude on Packaging Systems by Vacuum method |
| Ext Std ASTM | ASTM D3078-02 (R 2021) (E 2021) | Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission |
| Ext Std ASTM | ASTM F1929-15 | Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration |
| Ext Std ASTM | ASTM D6344-04 (2017) | Standard Test Method for Concentrated Impacts to Transport Packages |
| Ext Std ASTM | ASTM D5265-09 (2016) | Standard Test Method for Bridge Impact Testing |
| Ext Std ASTM | ASTM F17-20 | Standard Terminology Relating to Flexible Barrier Packaging |
| Ext Std ASTM | ASTM F2097-20 | Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products |
| EU Regulation | Regulation (EC) No 1272/2008 | Regulation on Classification, Labelling and Packaging of Substances and Mixtures |