## (A) Checklist for the grant of Import license in Form MD-15 for Medical Devices under Medical Devices Rules, 2017

| Form Type: | Fresh application in Form MD-14 |
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| **Section no.** | **Checklist Name** |
| 1 | Covering Letter |
| 2 | Application (Form MD-14) |
| 3 | Fee Challan |
| 4 | Power of Attorney along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in thecountry of origin or by an equivalent authority through apostille) |
| 5 | Copy of Whole Sale licence / Manufacturing licence / Registration Certificate in Form MD-42 of the Authorized agent |
| 6 | Constitution details of the authorized agent |
| **7** | **Regulatory Certificate** |
| 7.1 | Copy of Free Sale Certificate/Marketing Authorization of the productissued by the National Regulatory Authority of country of origin (if any) (duly notarized) |
| 7.2 | Copy of Free Sale Certificate Marketing Authorization of the productisued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia (duly notarized) |
| 7.3 | Copy of overseas manufacturing site / establishment / plant registration, by whatever name called, in the country of origin issuedby the competent authority (duly notarized) |
| 7.4 | Copy of latest inspection or audit report carried out by the Competent Authority within last 3 years, if any. |
| **8** | **Quality Certificate in respect of the actual manufacturing site, as applicable** |
| 8.1 | Copy of Certificate supporting Quality Management System (duly notarized) |
| 8.2 | Copy of Full Quality Assurance Certificate/ CE type examinationCertificate/ CE product quality assurance certificate, CE design Certificate, etc as applicable (duly notarized) |
| 8.3 | Declaration of conformity issued by the manufacturer |
| **9** | Plant Master file from the Manufacturer as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017 |
| **10** | **Device Master file from the Manufacturer as per Appendix II ofFourth Schedule of Medical Devices Rules, 2017** |
| 10.1 | Executive Summary |
| 10.2 | Descriptive information of the device |

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| 10.3 | Justification for the Medical Device Grouping |
| 10.4 | Product Specification, including variants, accessories, etc |
| 10.5 | Substantial equivalence with reference to the predicate device or previous generations of the device |
| 10.6 | Labelling information (Labels, Instruction for Use, etc) |
| 10.7 | Device Design and Manufacturing Information |
| 10.8 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device |
| 10.9 | Risk analysis and control summary |
| 10.1 | Verification and validation of the medical device |
| 10.11 | Biocompatibility validation data (if applicable) |
| 10.12 | Medicinal substances data (if device contains Drug) |
| 10.13 | Biological Safety (TSE/BSE), if applicable |
| 10.14 | Sterilization Validation data (if applicable) |
| 10.15 | Software verification and validation (if software used) |
| 10.16 | Animal studies – Preclinical data (if any) |
| 10.17 | Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable) |
| 10.18 | Clinical evidence (if any) |
| 10.19 | Post Marketing Surveillance data (Vigilance reporting) |
| 10.20 | Batch Release Certificates or Certificate of Analysis for minimum 3consecutive batches/ Software version release certificate |
| **11** | Any other additional documents |
| **12** | Copy of Permission in Form MD-27 (incase of Investigational Medical Device ) |

## B) Checklist for the grant of Import license in Form MD-15 for additional Medical Devices under Medical Devices Rules, 2017

| **Form Type:** | **Endorsement application in Form MD-14** |
|---|---|
| **Section no.** | **Checklist Name** |
| **1** | Covering Letter |
| **2** | Application (Form MD-14) |
| **3** | Fee Challan |
| **4** | Power of Attorney along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in thecountry of origin or by an equivalent authority through apostille) |
| **5** | Copy of Import License obtained for which the endorsement is applied |
| **6** | **Regulatory Certificate** |
| 6.1 | Copy of Free Sale Certificate/Marketing Authorization of the productissued by the National Regulatory Authority of country of origin (if any) (duly notarized) |
| 6.2 | Copy of Free Sale Certificate Marketing Authorization of the productisued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia (duly notarized) |
| **7** | **Quality Certificate in respect of the actual manufacturing site, as applicable (duly notarized)** |
| 7.1 | Copy of Certificate supporting Quality Management System |
| 7.2 | Copy of Full Quality Assurance Certificate/ CE type examinationCertificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable |
| 7.3 | Declaration of conformity issued by the manufacturer |
| **8** | Undertaking from the overseas manufacturer stating that there is no major change(s) in the existing Plant Master File (PMF). Otherwise, information as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017 needs to be submitted. |
| **9** | **Device Master file from the Manufacturer as per Appendix II ofFourth Schedule of Medical Devices Rules, 2017** |
| 9.1 | Executive Summary |
| 9.2 | Descriptive information of the device |
| 9.3 | Justification for the Medical Device Grouping |
| 9.4 | Product Specification, including variants, accessories, etc |
| 9.5 | Substantial equivalence with reference to the predicate device or previous generations of the device |
| 9.6 | Labelling information (Labels, Instruction for Use, etc) |
| 9.7 | Device Design and Manufacturing Information |

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| 9.8 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device |
| 9.9 | Risk analysis and control summary |
| 9.1 | Verification and validation of the medical device |
| 9.11 | Biocompatibility validation data (if applicable) |
| 9.12 | Medicinal substances data (if device contains Drug) |
| 9.13 | Biological Safety (TSE/BSE), if applicable |
| 9.14 | Sterilization Validation data (if applicable) |
| 9.15 | Software verification and validation (if software used) |
| 9.16 | Animal studies – Preclinical data (if any) |
| 9.17 | Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable) |
| 9.18 | Clinical evidence (if any) |
| 9.19 | Post Marketing Surveillance data (Vigilance reporting) |
| 9.20 | Batch Release Certificates or Certificate of Analysis for minimum 3consecutive batches/ Software version release certificate |
| **10** | Any other additional documents |
| **11** | Copy of Permission in Form MD-27 (incase of Investigational Medical Device ) |

## (C) Checklist for the retention of import license granted in Form MD-15 for Medical Devices under Medical Devices Rules, 2017

| Form Type: | Retention application for Form MD-15 |
|---|---|
| **Section no.** | **Checklist Name** |
| 1.0 | Covering letter |
| 2.0 | Duly Signed Retention Form |
| 3.0 | Fee Challan |
| 4.0 | Copy of the existing Import licence or its retention (if obtained) |
| 5.0 | Copy of endorsement(s) to the existing Import license |
| 6.0 | List of the device(s) deleted from the existing Import license along with the reason |
| 7.0 | Detailed breakup of the fees deposited in terms of site, risk class of the device and Medical device grouping etc. |
| 8.0 | An undertaking from the manufacturer stating that there is no major change(s) in the existing Device Master File (DMF) and Plant Master File (PMF) |
| 9.0 | Post marketing surveillance data (Vigilance reporting) during last 5 yrs (details of complaints, recall (if any), CAPA taken, etc), dulyauthenticated by the manufacturer or authorized agent. |
| 10.0 | Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any), (duly notarized) |
| 11.0 | Copy of Free Sale Certificate Marketing Authorization of the product isued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia (duly notarized) |
| 12.0 | Copy of Certificate supporting Quality Management System |
| 13.0 | Copy of Full Quality Assurance Certificate/ CE type examinationCertificate/ CE product quality assurance certificate, CE design Certificate, etc as applicable |
| 14.0 | Declaration of conformity issued by the manufacturer |
| 15.0 | An undertaking by the manufacturer and authorized agent, stating that they have agreed for retention of the Import License Number, for applied products |
| 16.0 | Undertaking by the manufacturer and authorized Indian agent stating that there is no change in the Power of Attorney (POA).<br>In case any change, a fresh POA along with undertaking from theauthorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille) shall be submitted. |
| 17.0 | Undertaking from the foreign manufacturer as well as from the authorized agent stating that there is no change in the Constitution of the firm |
| 18.0 | Undertaking stating that they shall submit the requisite fees for allthe products endorsed in the base license before completion of the five years from the date of issue of the base license. |
| 19.0 | Post Approval Changes taken due to change in name and/or address of the firm, product details (if any) |