

CHECKLIST

Form Name: Post Approval Change application for Import License (Form MD- 14)

Category: Change in respect of material of construction

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Comparative statement between existing and proposed material of construction along with justification/rationale for proposed change	Yes
3.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
4.	Revised Label, Instruction For Use, package insert, product manual with proposed change (if applicable)	Yes
5.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
6.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed change (if any)	Yes
7.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
8.	Risk Management report on the device	Yes
9.	Stability study report (if applicable)	Yes
10.	Biocompatibility data (if applicable)	No
11.	Other document, if any	No

Category: Change of address of the overseas legal manufacturer (without change in the constitution)

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Reason for proposed change	Yes
3.	Upload existing Import License and its retention if applicable	No
4.	Copy of Power of Attorney along with undertaking from authorized agent 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	Yes
5.	Legal undertaking from the manufacturer stating that there is no change in the Constitution of Overseas Manufacturer, except the address of the manufacturer and the same may be read in place of previous address in all Technical documents submitted at the time of grant of license.	Yes
6.	Notarized copy of overseas manufacturing site or establishment or plant registration from the country of origin issued by competent of the country	Yes
7.	Notarized copy of Free Sale Certificate issued by the national regulatory authority or other competent authority of any of the countries namely, USA, EU, UK, Canada, Australia or Japan	Yes
8.	Notarised copy of all Quality certificates (ISO 13485, CE Certificate, etc) with change in name	Yes
9.	Other document, if any	No

Category: Change of address of the overseas actual manufacturer (without change in the location and constitution)

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Reason for proposed change	Yes
3.	Upload existing Import License and its retention if applicable	Yes
4.	Copy of Power of Attorney along with undertaking from authorized agent 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	Yes
5.	Legal undertaking from the manufacturer stating that there is no change in the Constitution of Overseas Manufacturer, except the address of the manufacturer and the same may be read in place of previous address in all Technical documents submitted at the time of grant of license.	Yes
6.	Notarized copy of overseas manufacturing site or establishment or plant registration from the country of origin issued by competent of the country	Yes
7.	Notarized copy of Free Sale Certificate issued by the national regulatory authority or other competent authority of any of the countries namely, USA, EU, UK, Canada, Australia or Japan	Yes
8.	Notarised copy of all Quality certificates (ISO 13485, CE Certificate, etc) with change in name	Yes
9.	Other document, if any	No

Category: Change in respect of model number of the devices

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Details of proposed model number of the device	Yes
3.	Comparative statement between existing and proposed model number along with justification/rationale for addition of model number	Yes
4.	Upload existing Import License and its retention if applicable	Yes
5.	Reference to predicate or similar device available in the country	Yes
6.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
7.	Risk Management report on proposed model number of the device	Yes
8.	Labelling information of proposed model number of the device	Yes
9.	Test reports as per applicable standards	Yes
10.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
11.	Notarized copy of Free Sale Certificate issued by the national regulatory authority or other competent authority of any of the countries namely, USA, EU, UK, Canada, Australia or Japan	Yes
12.	Notarized copy of all Quality certificates (ISO 13485, CE Certificate, etc)	Yes
13.	Other relevant document (if any)	No

Category: Change in respect of Accessories / components of the devices

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Details of proposed accessories of the parent device	Yes
3.	Comparative statement between existing and proposed accessories along with justification/rationale for addition of accessories to the parent device	Yes
4.	Upload existing Manufacturing License and its retention if applicable	Yes
5.	Copy of the Device Master File highlighting the proposed accessories	Yes
6.	Risk Management report of the parent device with respect to the proposed accessories	Yes
7.	Copy of Instructions for use/ User manual/ Package insert highlighting the proposed accessories	Yes
8.	Notarized copy of Free Sale Certificate issued by the national regulatory authority or other competent authority of any of the countries namely, USA, EU, UK, Canada, Australia or Japan	Yes
9.	Other relevant document (if any)	No

Category: Change in respect of Primary packaging material

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed primary packaging material along with justification/rationale for the change	Yes
2.	Upload existing Import License and its retention if applicable	Yes
3.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed changes (if any)	Yes
4.	Risk Management report on the device	Yes
5.	Packaging and Sterilization validation report (wherever applicable)	Yes
6.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
7.	Accelerated stability and on-going real time stability study data (if applicable)	Yes
8.	Other document, if any	No
9.	Application for PAC	Yes

Category: Change in the method of Sterilization

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed method of sterilization along with justification/rationale for proposed changes	Yes
2.	Upload existing Import License and its retention if applicable	Yes
3.	Revised Labelling information (wherever applicable)	Yes
4.	Copy of the relevant amendment in the Device Master File	Yes
5.	Risk Management report on the device	Yes
6.	Sterilization validation report	Yes
7.	Accelerated Stability study and On-going real time stability study report	Yes
8.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
9.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed change (if any)	Yes
10.	Other document, if any	No
11.	Application for PAC	Yes

Category: Change of the approved Shelf Life

Section no.	Checklist Name	Is Mandatory
1.	Covering Letter,	Yes
2.	Justification/Rationale for Changes,	Yes
3.	Upload Old License,	Yes
4.	Labels and IFU,	Yes
5.	Comparative chart between Approved and Proposed Shelf Life,	Yes
6.	Stability study data of proposed IVDMD made with the proposed composition / content ,	No
6.1	Claimed Shelf life - stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion.,	Yes
6.2	In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion	Yes
6.3	Shipping stability study report for 1 lot including the protocol, acceptance criteria, simulated conditions, conclusion and recommended shipping conditions	Yes
7.	Approval for the changes from National Regulatory Authority or equivalent competent authority based upon whose Free sale certificate, Registration certificate/ Import license was obtained initially,	Yes
8.	List of Countries where the proposed change has been approved Regulatory Authority or equivalent competent authority ,	Yes
9.	Other documents, if any,	No

Category: Change in the Intended use or indication for use

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement of the existing and proposed intended use of indication for use of the IVD Medical device along with justification /rationale for proposed change	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
3.	Clinical evidence on proposed change	Yes
4.	Revised labelling and IFU information	Yes
5.	Reference to predicate or similar device available in the market in respect of proposed intended use/indication for use	Yes
6.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
7.	Risk Management report on the device	Yes
8.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed change	Yes
9.	Other document, if any	No
10.	Application for PAC	Yes

Category: Change in respect of design which shall affect quality in respect of its specifications, indication for use, performance and stability of the medical device

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed design of the device along with justification/rationale for proposed change	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
3.	Revised Labelling information (if any)	No
4.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
5.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed change (if any)	Yes
6.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
7.	Risk Management report on the device,	Yes
8.	Stability study report (if applicable)	No
9.	Device design verification and validation report	Yes
10.	Other document, if any	No
11.	Application for PAC	Yes

Category: Change in respect of Label excluding change in font size, font type, color, label design

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed label of the device along with justification/rationale for proposed changes	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	No
3.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed changes (if any)	No
4.	Copy of revised label of the device	Yes
5.	Packaging validation data (if applicable)	No
6.	Application for PAC	Yes

Category: Change in respect of the Instructions for Use or User manual or package insert

Section no.	Checklist Name	Is Mandatory
1.	Comparison between existing and proposed Instructions for use/User manual/Package insert (highlighting the proposed changes) along with justification/rationale for proposed changes	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
3.	Revised Instructions for use/User manual/Package insert	Yes
4.	Risk Management report on the device (if applicable)	Yes
5.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed changes (if any)	Yes
6.	Other document, if any	No
7.	Application for PAC	Yes

Category: Change in respect of the manufacturing process, equipment or testing which shall affect quality of the device

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and new manufacturing process/ equipment/ testing along with justification/rationale for proposed changes	Yes
2.	Upload existing Import License and its retention if applicable	Yes
3.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed changes (if any)	Yes
4.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
5.	Quality Management System certificate issued by the competent authority	Yes
6.	Validation and verification data of new manufacturing process/ equipment/ testing	Yes
7.	Other document, if any	No
8.	Application for PAC	Yes

Category: Change of name of the overseas manufacturer or its manufacturing site
(without change in the constitution)

Section no.	Checklist Name	Is Mandatory
1.	Application for PAC	Yes
2.	Reason for proposed change	Yes
3.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
4.	Copy of Power of Attorney along with undertaking from authorized agent 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	Yes
5.	Legal undertaking in 100 Rs Stamp paper from the manufacturer stating that there is no change in the Constitution of Overseas Manufacturer, except the name of the manufacturer and the same may be read in place of previous name in all Technical documents submitted at the time of grant of license	No
6.	Notarized copy of overseas manufacturing site or establishment or plant registration from the country of origin issued by competent of the country	Yes
7.	Notarized copy of Free Sale Certificate issued by the national regulatory authority or other competent authority of any of the countries namely, USA, EU, UK, Canada, Australia or Japan	No
8.	Notarised copy of all Quality certificates (ISO 13485, CE Certificate, etc) with change in name	Yes
9.	Revised Label, Instruction For Use, package insert, product manual with proposed change (if applicable)	No
10.	Revised Plant Master File with proposed change	No

Category: Change of name of the authorized agent (Without change in the constitution)

Section no.	Checklist Name	Is Mandatory
1.	Covering Letter,	Yes
2.	Power of Attorney (Original) 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 along with under taking from the authorized agent as specified in Part I of Forth Schedule,	Yes
3.	Constitution details of authorized agent,	Yes
4.	Upload Old License,	Yes
5.	Label and IFU and Labels with Indian Specific details,	Yes
6.	Self-attested copy of valid Whole sale licence or manufacturing licence,	Yes
7.	Other documents, if any,	No

Category: Change of address of the authorized agent (Without change in the constitution)

Section no.	Checklist Name	Is Mandatory
1.	Covering Letter,	Yes
2.	Power of Attorney (Original) 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 along with under taking from the authorized agent as specified in Part I of Forth Schedule,	Yes
3.	Constitution details of authorized agent ,	Yes
4.	Upload Old License,	Yes
5.	Labels and IFU,	Yes
6.	Self-attested of valid wholesale License or manufacturing License,	Yes
7.	Legal Form	Yes

Category: Change in respect of design which shall not affect quality in respect of its specifications, indication for use, performance and stability of the medical device

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed design of the device along with justification/rationale for proposed change	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
3.	Revised Labelling information (if any)	Yes
4.	Batch Release Certificates or Certificate of Analysis of finished product for minimum three consecutive batches	Yes
5.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed change (if any)	No
6.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
7.	Risk Management report on the device	Yes
8.	Stability study report (if applicable)	Yes
9.	Device design verification and validation report	Yes
10.	Other document, if any	No
11.	Application for PAC	Yes

Category: Change in respect of the manufacturing process, equipment, or testing which shall not affect quality of the device

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and new manufacturing process/ equipment/ testing along with justification/rationale for proposed changes	Yes
2.	Upload existing Import License and its retention if applicable	Yes
3.	Notarized copy of approval obtained from National Regulatory Authority/Notified body for proposed changes (if any)	Yes
4.	Copy of the relevant amendment in the Plant Master File (if applicable)	Yes
5.	Copy of the relevant amendment in the Device Master File along with Essential Principles Checklist of the device	Yes
6.	Validation and verification data of new manufacturing process/ equipment/ testing	Yes
7.	Other document, if any	No
8.	Application for PAC	Yes

Category: Change in respect of the packaging specifications excluding primary packaging material

Section no.	Checklist Name	Is Mandatory
1.	Comparative statement between existing and proposed packaging specification along with justification/rationale for change	Yes
2.	Upload existing Import License and its retention along with covering letter (if applicable)	Yes
3.	Copy of revised label and IFU of the device (if applicable)	Yes
4.	Risk Management report on the device (if applicable)	Yes
5.	Packaging validation data (if applicable)	Yes
6.	Other document, if any	No
7.	Application for PAC	Yes
8.	Copy of relevant amendment in the Device Master File (if applicable)	Yes

Category: Amendment / Correction/ Others

Section no.	Checklist Name	Is Mandatory
1.	Covering Letter	Yes
2.	Copy of earlier licence	Yes
3.	copy of earlier MD-14	Yes
4.	proposed change/correction	Yes
5.	Reason/justification for change	Yes
6.	copy of earlier fee receipt	Yes