**Documents for notification request (manufacturer), type FULL**

| number | Supporting Documents | condition |
|---|---|---|
| 1 | Device Labeling* according to the announcement, labels and Documentation for medical devices** | Force attachment |
| 2 | Medical device documentation* (if any) according to the announcement, labels and documents directing medical | Optional |
| 3 | devices Product specifications specifications)** General characteristics | Force attachment |
| 4 | and working principles (Device Description and features)** | Force attachment |
| 5 | Description and properties of the materials used in the manufacture or composition of Medical devices (Materials)** | Force attachment |
| 6 | Declaration of conformity according to Form 1** | Force attachment |
| 7 | Document showing history of registration abroad In the event that there is Overseas registration | Optional |
| 8 | Documents showing sterility testing in case of manufacture or import CPSC, sterile | Optional |
| 9 | Documents showing test or calibration in case of manufacture or import CPSC used for | Optional |
| 10 | measurement The document lists the grouped medical devices. and explain the reason Medical device bundles (if any) Other | Optional |
| 11 | attachments 1 Other attachments 2 | Optional |
| 12 | Other attachments 3 Other | Optional |
| 13 | attachments 4 Other attachments 5 | Optional |
| 14 | | Optional |
| 15 | | Optional |

**Documents attached to the request for declaration of details (manufacturer), type Partial 2**

| number | Supporting Documents | condition |
|---|---|---|
| 1 | Device Labeling* according to the announcement, labels and Documentation for medical devices** | Force attachment |
| 2 | Medical device documentation* according to the announcement, labels and accompanying documents Medical device** | Force attachment |
| 3 | Summary of medical devices** The details must be as follows: (1) Brief overview of medical devices (2) Table showing history of medical devices has been approved to be registered or allowed to be sold in the market and distribution history in various countries (3) Table showing details of the revocation (if any). (4) A table showing the status of the request. registered or licensed to sell the product in an active market, or In the process (if any) (5) Table showing the incident report If you wish to use the medical device, please attach a detailed document. of AE (6) table showing field safety corrective action report (FSCAs), a document specifying the details of the FSCAs (7) report must be attached. Show the details of the medical device. In the following cases, contains a cell, tissue or derivative of a human or animal that has been rendered non-viable, containing a cell, tissue or derivative of valence. microbial or recombinant origin, containing irradiating component of ionic type | Force attachment |
| 4 | Details of the medical device** must contain the following details: (1) Characteristics General and working principle (2) Purpose of use (3) Indications (4) Instructions for use (5) Storage (6) Shelf life (7) b Do not use (8) Warning (9) Caution (10) Unwanted consequences (11) Alternative treatment (12) Description and properties of the materials used for manufacture. or as a component of a medical device (13) Medical devices (product specifications) | Force attachment |
| 5 | Document showing the name and location of the medical device manufacturing facility. (Flow chart) in the overview of the production process, control, assembly, testing, finished product, packing, labeling, Storage, sterilization (if any) and related processes and detailed production data for each process shown in the diagram. or display the name and location of the product owner** | Force attachment |

| | | |
|---|---|---|
| 6 | document destruction method invalidation or eliminating waste generated<br>After use (if any) | Optional |
| 7 | Certificate of Quality Manufacturing ISO 13485 or GMP Medical Devices<br>(In the case of a medical device in the country of manufacture or the product | Force attachment |
| 8 | owner** Other quality certificates such as ISO 9001 (in the case of not a medical device)<br>physician in the country of manufacture or the product owner)** | Force attachment |
| 9 | Declaration of conformity according to the form** Other | Force attachment |
| 10 | attachments 1 Other attachments 2 | Optional |
| 11 | | Optional |

## Documents for permission request (manufacturer) Partial 2

| number | Supporting Documents | condition |
|---|---|---|
| 1 | Device Labeling* according to the announcement, labels and<br>Documentation for medical devices** | Force attachment |
| 2 | Medical device documentation* according to the announcement, labels and accompanying documents<br>Medical device** | Force attachment |
| 3 | Summary of medical devices** The details are as follows: (1) Brief overview of<br>medical devices. (2) Table showing history of medical devices.<br>has been approved to be registered or allowed to be sold in the market and<br>distribution history in various countries (3) Table showing details<br>of the revocation (if any). (4) A table showing the status of the request.<br>registered or licensed to sell the product in an active market, or<br>In the process (if any) (5) Table showing the incident report<br>If you do not wish to use the medical device, please attach a document specifying the details.<br>of AE (6) table showing field safety corrective action report<br>(FSCAs), a document specifying the details of the FSCAs (7) report must be attached.<br>Show the details of the medical device. In the following cases, contains a cell,<br>tissue or derivative of a human or animal that has been rendered non-viable, containing<br>a cell, tissue or derivative of a cell. microbial or recombinant origin, containing<br>irradiating component of ionic type | Force attachment |
| 4 | Details of the medical device** must contain the following details: (1) Characteristics<br>General and working principles (2) Purpose of use (3) Indications (4) | Force attachment |

| | | |
|---|---|---|
| | Instructions for use (5) Storage (6) Shelf life (7) Contraindications (8) Warning (9) Caution (10) Unfavorable results Desired from use (11) Alternative treatment (12) Description and properties of the materials used for manufacture. or as a component of a medical device (13) Medical devices (product specifications) | |
| 5 | Document showing the name and location of the medical device manufacturing facility. (Flow chart) in the overview of the production process, control, assembly, testing, finished product, packing, labeling, Storage, sterilization (if any) and related processes and detailed production data for each process shown in the diagram. or display the name and location of the product owner** | Force attachment |
| 6 | Risk Management Report comply with the ISO standard 14971** | Force attachment |
| 7 | document destruction method invalidation or eliminating waste generated After use (if any) | Optional |
| 8 | Certificate of Quality Manufacturing ISO 13485 or GMP Medical Device (In the case of a medical device in the country of manufacture or the product owner** | Force attachment |
| 9 | Other quality certificates such as ISO 9001 (in the case of not a medical device) physician in the country of manufacture or the product owner)** | Force attachment |
| 10 | Declaration of conformity according to the form** | Force attachment |
| 11 | Other attachments 1 Other attachments 2 | Optional |
| 12 | | Optional |

**Documents attached to the request for declaration of details / permission (manufacturer) type FULL**

| number | Supporting Documents | condition |
|---|---|---|
| 1 | Label of medical devices (Device Labeling) * According to the announcement, labels and Documentation for medical devices** | Force attachment |
| 2 | Medical device documentation* according to the announcement, labels and accompanying documents Medical device** | Force attachment |
| 3 | Summary of medical devices** The details are as follows: (1) Brief overview of medical devices. (2) Table showing history of medical devices. has been approved to be registered or allowed to be sold in the market and distribution history in various countries (3) Table showing details of the revocation (if any). (4) A table showing the status of the request. registered or licensed to sell the product in an active market, or In the process (if any) (5) Table showing the incident report If you do not wish to use the medical device, please attach a document specifying the details. of AE (6) table showing field safety corrective action report (FSCAs), a document specifying the details of the FSCAs (7) report must be attached. Show the details of the medical device. In the following cases, contains a cell, tissue or derivative of a human or animal that has been rendered non-viable, containing a cell, tissue or derivative of a cell. microbial or recombinant origin, containing irradiating component of ionic type | Force attachment |
| 4 | Details of the medical device** must contain the following details: (1) Characteristics General and working principle (2) Purpose of use (3) Indications (4) Instructions for use (5) Storage (6) Shelf life (7) b Do not use (8) words Warning (9) Caution (10) Unwanted Consequences (11) Alternative treatment (12) Description and properties of the materials used for manufacture. or as a component of a medical device (13) Medical devices (product specifications) | Force attachment |
| 5 | Document showing the name and location of the medical device manufacturing facility. (Flow chart) in the overview of the production process, control, assembly, testing, finished product, packing, labeling, Storage, sterilization (if any) and related processes and detailed production data for each process shown in the diagram. or display the name and location of the product owner** | Force attachment |

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|---|---|---|
| 6 | Essential Principles** | Force attachment |
| 7 | Summary Verification & validation** Certificate of | Force attachment |
| 8 | purpose of use Indications of use Packing certificate<br>Manufacturer's or product owner's label and instructions for use** Risk | Force attachment |
| 9 | Management Report comply with the ISO standard<br>14971** | Force attachment |
| 10 | document destruction method invalidation or eliminating waste generated<br>After use (if any) ** Certificate | Force attachment |
| 11 | of production quality ISO 13485 or GMP medical device (In the case of a medical device in<br>the country of manufacture or the product owner** Other quality certificates such as ISO | Force attachment |
| 12 | 9001 (in the case of not a medical device)<br>physician in the country of manufacture or the product owner) ** | Force attachment<br>Force attachment |
| 13 | Certificate showing CPSC sales history of the manufacturer or owner<br>Product** | |
| 14 | Certificate showing the safety of the manufacturer or the product owner in foreign countries | Force attachment |
| 15 | that have been approved by the FDA** | Force attachment |
| 16 | Declaration of conformity according to the form** Other | Force attachment |
| 17 | attachments 1 Other attachments 2 | Optional |
| 18 | | Optional |