



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
 KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
 Portal: www.mdb.gov.my
 Email: mdb@mdb.gov.my

NOTIFICATION FOR UNREGISTERED CUSTOM MADE MEDICAL DEVICES

(In accordance with Medical Device (Exemption) Order 2016)

All field are mandatory unless stated otherwise

SECTION A: SPONSOR DETAILS

(The Sponsor is the individual, institution or organization who takes responsibilities for the importation and/or supply the custom-made medical device in Malaysia)

1. Please tick the appropriate box:

- Local custom-made manufacturer
- Local health professional *(obtains directly from the custom-made manufacturer for supply to his/her patient)*
- An authorized person from a local organization/company *(Note: shall have business operation in Malaysia)*
- Others *(please specify):*

2. Name of Applicant:

3. NRIC No./Passport:

4. Designation:

5. Name & Address of Organization:

6. Telephone No.:

7. Email Address:

8. Does the company already holds Establishment License or has submitted establishment license application *(if applicable)?*

Yes

No

If Yes, please state the company Establishment License Number or From Identification (Form ID):

Company's Role:

- Local Manufacturer
- Authorized Representative
- Distributor
- Importer

SECTION B: PRESCRIBER DETAILS

Note: Medical Practitioner; OR Healthcare Professional User (e.g.: Dentist, Optometrist, Orbital Prosthetist, Ocularist, Audiologist, Orthotist, Orthopaedic Shoe Fitter, or Hearing Aid Dispenser)

1. Name:

2. Title:

3. Annual Practicing Certificate Number:

4. Telephone No.:

5. Email Address:



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6. Health Care Facility Name & Address:

SECTION C: CUSTOM MADE MEDICAL DEVICE MANUFACTURER DETAILS

NOTE : Manufacturer is the legal person with responsibility for the design, manufacture, packaging and labelling of the device under his own name before it is placed on the market)

1. Name & Address of Organization:

2. Contact person:

3. Contact details:

Email:

Phone/Fax Number:

SECTION D: CUSTOM MADE MEDICAL DEVICE DETAILS

*Note : Mass-produced devices, which need to be adapted to meet the specific requirements of a healthcare professional (and which are supplied for the sole use of a particular patient), are **not** considered to be custom-made devices*

Please provide details of the medical device in **Appendix A**

Please provide following supporting document:

- A copy of statements for custom-made medical device that contain information about the description, serial number, name of the patient, name of the authorized person who made the prescription, the name and address of the manufacturer, etc.

SECTION E: PATIENT DETAILS

Patient's ref No (MRN /HIS):

SECTION F: ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that

- This/These product(s) is/are a medical device in accordance to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).
- This/These product(s) has/have met the definition of a custom-made medical device that are:
 - Has been manufactured specifically in accordance with a written specification by a health professional specifying its design characteristic or construction.



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- Intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice
- iii. The medical device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.
- iv. The medical device(s) has/have met all the labelling requirements set out in the Sixth Schedule of the MDR 2012.
- v. The technical documentation of the custom made device(s) is/are prepared in accordance with the *format* as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.
- vi. Manufacturing Process

Remark: Any kind of deletion in Section F please provide justification

I shall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and performance of this/these medical device(s).

I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding RM **500,000.00** or to imprisonment for a term not exceeding **3 years** or to both. (S.76 Act 737 refers).

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :



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Appendix A:

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|--|---|--------------------------|----------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------------|-------|--------------------------|-------|--------------------------|-------|--|-------|--|-------|--|-------|--|-------|--|-------|--|-------|
| Name of Medical Device: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical Device Grouping: | <input type="checkbox"/> Single <input type="checkbox"/> System <input type="checkbox"/> Family <input type="checkbox"/> Set | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical Device Description: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brand/ Model: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Model: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intended use of the medical device: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Manufacturer's Name <i>(as it appears on the label) :</i> | | | | | | | | | | | | | | | | | | | | | | | | | |
| Class: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Classification Rule: (according to First Schedule on Rules of Classification of Medical Device, MDR 2012) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Marketing Approval Status in other country(-ies) (Please state the name (s) of country (ies) and provide supporting documents as evidence) | <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;"><input type="checkbox"/></td> <td style="width: 25%;">Registered /Licensed</td> <td style="width: 25%;"><input type="checkbox"/></td> <td style="width: 25%;">Exempted/ Notified</td> <td style="width: 25%;"><input type="checkbox"/></td> <td style="width: 25%;">Others (please specify)</td> </tr> <tr> <td><input type="checkbox"/></td> <td>.....</td> <td><input type="checkbox"/></td> <td>.....</td> <td><input type="checkbox"/></td> <td>.....</td> </tr> <tr> <td></td> <td>.....</td> <td></td> <td>.....</td> <td></td> <td>.....</td> </tr> <tr> <td></td> <td>.....</td> <td></td> <td>.....</td> <td></td> <td>.....</td> </tr> </table> | <input type="checkbox"/> | Registered /Licensed | <input type="checkbox"/> | Exempted/ Notified | <input type="checkbox"/> | Others (please specify) | <input type="checkbox"/> | | <input type="checkbox"/> | | <input type="checkbox"/> | | | | | | | | | | | | | |
| <input type="checkbox"/> | Registered /Licensed | <input type="checkbox"/> | Exempted/ Notified | <input type="checkbox"/> | Others (please specify) | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | |
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| Medical Device usage category (please tick the appropriate box) | <input type="checkbox"/> Dental Appliances | <input type="checkbox"/> Artificial Eyes/Cosmetic Shells | |
|---|--|--|----------------------------|
| | <input type="checkbox"/> Maxillofacial Prosthesis | <input type="checkbox"/> Hearing Aid Inserts/Moulds | |
| | <input type="checkbox"/> In-the-Ear Aids | <input type="checkbox"/> Orthopaedic Footwear | |
| | <input type="checkbox"/> Joint Replacement Implants | <input type="checkbox"/> Prosthetics and Orthotics | |
| | <input type="checkbox"/> Others (please specify): | | |
| Grouping List: | Not Applicable to single medical device | | |
| No. | Name of medical device, accessories, components, or articles as per product label: | Model | Medical Device Description |
| | | | |
| | | | |