**Agreement between a single legal manufacturer and an authorized representative**

**manufacturer and an authorized representative**

*[To be printed on Manufacturer Letterhead]*

AGREEMENT FOR AUTHORIZED

REPRESENTATIVE SERVICES

**Parties to the Agreement:**

**Manufacturer**: ……………………………………………

established in *[insert postal address to establish location*]

Address 1:………………………………………….
Address 2: …………………………………………
City: ……………………………………………….
Postal Code: ……………………………………….
Country: ……………………………………………
Telephone Number: ………………………………..
Fax Number: ……………………………………….

The name and position of the authorized person to open the overseas manufacturer account and submit applications for medical device marketing authorization………………………….

The official email of the Manufacturer...…............

and

**Authorized Representative**:………………………………

established in *[insert postal address to establish location*]

Address 1:………………………………………….
Address 2: …………………………………………
City: ……………………………………………….
Postal Code: ……………………………………….
Country: ……………………………………………
Telephone Number: ………………………………..
Fax Number: ……………………………………….

A. **Definitions**

Manufacturer: Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.

Authorized Representative: A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.

B. **Governing Law**

This agreement is subject to the laws of the KSA.

C. **Applicable Medical Device Regulation**

The Medical Devices Law issued by Royal Decree No. (M/54) dated 18 February 2021, and Implementing Regulation of Medical Devices Law issued by the Saudi Food and Drug Authority Board of Directors’ Decree No. (3-29-1443) dated 19/2/1443H.

D. **Tasks of the Authorized Representative**

The authorized representative shall:

a. Represent the manufacturer in its dealings with the SFDA.

b. List each medical device category or generic device group intended to be supplied to the KSA market, as required by the Medical Device Law, and It’s Implementing Regulation.

c. Complete the electronic marketing authorized application through the "GHAD System on the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by (MDS-REQ 1) Requirements for Medical Devices Marketing Authorization.

d. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in (MDS-REQ 11) Requirements for Post-Market Surveillance of Medical Devices

e. Make the following information available to the SFDA when so required in relation to its market surveillance activities:

• The marketing authorization issued by the SFDA for the listed medical devices.

• The documentation which was used to demonstrate compliance with the SFDA requirements.

• The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to Requirements for ***Medical Devices Marketing Authorization (MDS-REQ 1).***

f. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.

g. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.

h. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.

 E. **Responsibilities of the Manufacturer**

The manufacturer shall:

Create an overseas manufacturer account through SFDA electronic services to submit applications for medical device marketing authorization or delegate the authorized representative for medical device marketing authorization.

 Not have more than one authorized representative for the same medical device.

*[List the commitments and responsibilities of the manufacturer that will enable the authorized representative to perform the tasks listed in D in an efficient and effective manner]*

F. **Medical Devices**

The manufacturer designates the authorized representative to act on its behalf for one or more of the medical device categories indicated in the table that follows.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active Implantable Devices  | Non-active Implantable Devices  |  |
|  | Anaesthetic and Respiratory Devices  | Dental Devices  |  |
|  | Ophthalmic and optical devices  | Electro Mechanical Medical Devices  |  |
|  | Hospital Hardware  | In Vitro Diagnostic Devices  |  |
|  | Reusable Devices  | Single-use Devices  |  |
|  | Assistive Products for Persons with Disability  | Diagnostic and Therapeutic Radiation Devices  |  |
|  | Laboratory Equipment  | Healthcare Facility Products and Adaptations  |  |
|  | Complementary Therapy Devices  | Biologically Derived Devices  |  |
|  | Medical Software | Other Categories  |  |
| or generic device group as listed below  |

G. **Termination**

This agreement may be terminated by the **manufacturer** at any time provided it:

a. maintains the continuous presence of an authorized representative to represent it within the KSA. and

b. provides the authorized representative with a written notice of termination at least 45 days before the event.

This agreement may be terminated by the **authorized representative** at any time provided it:

1. undertakes to continue with the tasks specified in D until such time as the manufacturer appoints a licensed alternative to represent it within the KSA; and
2. provides the manufacturer with a written notice of termination at least 90 days before the event.

In the event of the SFDA terminating the authorized representative’s license, the authorized representative is expected to continue with the tasks specified in D until such time as the SFDA licenses an alternative authorized representative to represent the manufacturer within the KSA or for 90 days.

H. **Other Tasks and Provisions Additional to those Required for Au­thorized Representative Licensing**

*[List any tasks additional to those specified in D, that the manufacturer, under its sole responsibility, requires the authorized representative to undertake within the KSA. Such tasks are not assessed by the SFDA when it licenses the authorized representative]*

I. **Application Date**

This agreement shall enter into force on …………(dd/mm/yyyy)………

J. **Term of the Agreement**

This agreement shall remain in effect for ...... years from the date of application indicated in I, or until terminated by either party under the provisions of G.

K. **Attestation**

I, the undersigned, have the authority to accept the delegated tasks to be performed in the KSA, **on behalf of the authorized representative** named above, and ensure written procedures are applied to the tasks, where appropriate.

**Name:** ………………………..

**Signed:** ………………………..

**Position in organization:** ……………………………

**Date:** …………………………..

I, the undersigned, have the authority to agree **on behalf of the legal manufacturer** who is party to this agreement, to take without delay all measures necessary to allow the execution of the tasks delegated to the authorized representative.

I, the undersigned, declare that I have not designated any authorised representative other than that who is party to this agreement to act on my behalf for the medical devices listed in Section F.

**Name:** ………………………..

**Signed:** ………………………..

**Position in organization:** ……………………………

**Date:** …………………………..

Note:

1. **If the legal manufacturer is located outside the Kingdom of Saudi Arabia, the agreement shall be authenticated as the following:**
* **The country member of (Hague Convention):**

“Apostille” that been issued by an accredited body in the foreign country.

* **The country not member of (Hague Convention):**

A) Chamber of Commerce in foreign country.

B) The Ministry of Foreign Affairs in foreign country.

C) The Saudi embassy in the foreign country.

 D) The Saudi Foreign Ministry.

1. **If the legal manufacturer is located within the Kingdom of Saudi Arabia, the agreement shall be authenticated by all of the following parties:**

A) Chambers of Commerce and Industry.

B) The Embassy of the foreign party in the Kingdom.

C) The Saudi Foreign Ministry.