AGREEMENT FOR AUTHORIZED REPRESENTATIVE SERVICES

Parties to the Agreement:

Dixion

د ي ك س ي ن
ديكسين
Düsseldorf, Germany
40211
Bleichstr. 8-10

Represented by : Title :

And

Authorized Representative

TechnoMed

P.O Box 3161 Khobar 31952,

Kingdom of Saudi Arabia

Represented by : Title :

A. **Definitions**

For the purpose of this agreement, the **manufacturer** shall be the natural or legal person responsible for the medical devices he intends to place on the KSA market under his name and for which he already has the necessary authorization to legally place these devices on the market in one of the GHTF Founding Member jurisdiction.
Furthermore, the definitions specified in the Medical Devices Interim Regulation and its Implementing Rules shall apply.

B. **Governing Law**

This agreement is subject to the laws of the KSA.

C. **Applicable Medical Device Regulation**

The Interim Regulation for Medical Devices, issued by the Saudi Food and Drug Authority Board of Directors' Decree number 1-8-1429 dated 27 December 2008, published on 17 April 2009 in Umm AL-QURA Journal year 86 issue No 4249 and its relevant Implementing Rules.

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 Article 8 of the Implementing Rule MDS IR3 ***Medical Devices Listing.***

c. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 ***Marketing Authorization***.

d. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS - IR7 ***Post-marketing Surveillance***.

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

-The marketing authorisation issued by the SFDA for the listed medical devices.

-The documentation which was used to demonstrate compliance with the Regulation of the relevant GHTF founding member jurisdictions.

-The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of Implementing Rule MDS – IR 6 ***Marketing Authorization.***

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 Legal Manufacturers Subject to this Agreement**

The manufacturers shall:

Dixion shall provide its Authorized Representative with the information it requires to complete the appropriate marketing authorization electronic application form found on the SFDA website .and follow with him all post market surveillance to make sure manufacture and authorized representative comply with SFDA.

F. **Medical Devices**

The manufacturers designate the authorized representative to act on their 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 medical 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
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:

a. 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

b. 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**

NA

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, as party to this agreement, have the authority to agree **on behalf of the manufacturers listed below**, for them to take without delay all measures necessary to allow the execution of the tasks delegated to the authorized representative. Moreover, I accept the commitment to ensure each one of the listed manufacturers has a copy of this agreement and is aware of its particular tasks and responsibilities under its provisions. I, the undersigned, declare that I have not designated any authorized 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:

The agreement shall be authenticated by all of the following parties:

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.