## نموذج إقرار بمطابقة الإرسالية (الشحنة) لنظام الأجهزة والمستلزمات الطبية ولائحته التنفيذية

Declaration of Conformity for the Shipment

to Medical Devices and Supplies Law and its Executive Regulation

يطبع على الورق الرسمي

[To be printed on Manufacturer Letterhead]

Manufacturer Name: ……………………………………..……………...…………………………

Manufacturer Identification Number Assigned by the SFDA: ……………………………………..

Manufacturer Address: ……………………………………..………………………………….…..

Invoice Number (optional): ……………………………………..…………………………………

I hereby declare that the medical device/supply(s) identified below complies with the Medical Devices and Supplies Law and its Executive Regulation and has been authorized by the SFDA to be placed on the KSA market.

Authorized Representative Name: ………………………………….………………………….......

Importer Name: …………………………………………………………………………………….

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| # | Medical Device/Supply  Trade Name1 | Quantity | Serial Number/  Batch Number | Medical Device/Supply Listing National Registry Number  (mentined on the MDMA certificate) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| … |  |  |  |  |
| 1 Medical device/supply trade name shall match the names mentioned in the invoice and the “SFDA E-Services (Ghad)”.  Note: Additional devices may be attached as a list. | | | | |

Authorised Signatory (on behalf of the manufacturer)

Name:

Position:

Email:

Date:

Signature: