Agreement between a single legal manufacturer and an authorized representative

AGREEMENT FOR AUTHORIZED REPRESENTATIVE SERVICES

Parties to the Agreement:

Manufacturer: STEMA Medizintechnik GmbH

established in

Address 1: take-off GewerbePark 74 .....
Address 2: .....
City: Neuhausen ob Eck.....
Postal Code: 78579.....
Country: Germany.....
Telephone Number: +49 (0) 7467 79630 0.....
Fax Number: .....

The name and position of the authorized person to open the overseas manufacturer account and submit applications for medical device marketing authorization:
Markus Kramer, CEO
The official email of the Manufacturer: info@stema-medizintechnik.de

and

Authorized Representative: Aonkor international company

established in

Address 1: Abi Bakr Al Jalal 1,
Address 2: Al Dar Al Bayda District.....
City: Riyadh .....
Postal Code: .....
Country: Kingdom of Saudi Arabia (KSA).....
Telephone Number: +966 539 366 110

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Geschäftsführung
Markus Kramer
Steve Figger
Amtsgericht Stuttgart HRB 776
Ust.-Id. Nr.: DE 814114145

شركة أونكور انترناشونال
س.ت: ٧٠٥٣٠٥٩٩٩٩
C.R. 7053059999
AONKOR INTERNATIONAL COMPANY

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.

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Geschäftsführung
Markus Kramer
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Amtsgericht Stuttgart HRB 7749
Ust.-Id. Nr.: DE 814114585

• 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.

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	X
	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	

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	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:

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

I. Application Date

This agreement shall enter into force on 13th January 2026

J. Term of the Agreement

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

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Geschäftsführung
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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: Mshari Abdullah Al fraidi

Signed: .....

Position in organization: CEO

Date: 13th January 2026

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: Mr. Markus Kramer / STEMA Medizintechnik GmbH

Signed: .....

Position in organization: .....

Date: 13th January 2026

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شركة اونكور انترناشونال
س.ت: ٧٠٥٣٠٥٩٩٩٩
C.R.: 7053059999
AONNOR INTERNATIONAL COMPANY

UVZ 92/2026

UZ 107/2026

Notar Dr. Merschformann

Tuttlinger Str. 8 – 78333 Stockach – Tel.: 0 77 71 / 91 91 900 – E-Mail: kanzlei@notar-merschformann.de

Unterschriftsbeglaubigung

Vorstehende, vor mir als eigenhändig vollzogen anerkannte Unterschrift von

Herr Markus Frank Kramer, geboren am 19.04.1969,
geschäftsansässig: take-off GewerbePark 74 in 78579 Neuhausen ob Eck,

dem Notar von Person her bekannt

beglaubige ich hiermit öffentlich.

78333 Stockach, 22.01.2026

Notar Dr. Merschformann

DR. RALF MERSCHFORMANN
NOTAR IN STOCKACH

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. **Land:**
Country / Pays: Bundesrepublik Deutschland

Diese öffentliche Urkunde
This public document/Le présent acte public

2. **ist unterschrieben von**
has been signed by/a été signé par **Dr. Ralf Merschformann**

3. **in seiner/ihrer Eigenschaft als**
acting in the capacity of/agissant en qualité de Notar

4. **sie ist versehen mit dem Siegel/Stempel des/der**
bears the seal/stamp of/
est revêtu du sceau/timbre de Notars Dr. Merschformann in Stockach

Bestätigt
Certified/Attesté

5. **in**
at/à Konstanz

6. **am**
the/le 27.01.2026

7. **durch**
by / par die Vizepräsidentin des Landgerichts Dr. Schmieder beim Landgericht Konstanz

8. **unter Nr.**
N°/sous n° E 910 a (AR 66/26)

9. **Siegel/Stempel:**
Seal / stamp:
Sceau / timbre:

LANDGERICHT KONSTANZ

10. **Unterschrift:**
Signature:

LANDGERICHT KONSTANZ