



QMS N°: DIS/FMT/050
Rev. N°: 0
Effective date: 18/06/2020
Ref. Doc.: LAW N° 003/2018

CLINICAL TRIAL APPROVAL

(Made under law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning in its article 8, paragraph 7 and article 9, paragraph 2)

Clinical Trial Approval N°: 020/CTAC/FDA/2022

This is to certify that the clinical trial described below has been approved in Rwanda subject to conditions indicated in this certificate.

Protocol Title: **“A Clinical Investigation Evaluating Efficacy of an Intelligent Cardiotocography with Real-Time Alerts for an Improved Labor and Delivery”.**

Protocol Number: **SPIKER/RW/CT/CTG-AI | version 0.2**

Name of the Investigational product (s):

Intervention (s)	Comparator (s)
• SPIKER AI-CTG(or EDAN CTG F9 powered by SPIKER AI)	• EDAN CTG F9

Clinical Trial site (s): **La Croix du Sud Hospital, KIGALI.**

Name of the Principal Investigator(s):
Dr. Kizito NKURIKIYEYEU, PhD.

CRO/Research Institution (s): **N/A**

Sponsor's name: **Spiker Ltd, Japan.**

Issued On: **11 /10/2022**

Expires on: **10/10/2023**

Dr. Emile BIENVENU
Director General



Key Conditions for compliance

1. To comply with eligibility criteria while recruiting participants as per trial protocol
2. To provide sufficient information to participant before recruitment for freely participation
3. The Informed consent should always be obtained from the participant prior to enrollment
4. Changes, amendment, addendum to the study protocol or consent must be approved by Rwanda FDA prior to the implementation
5. Any Serious Adverse Events (SAEs) shall be notified to Rwanda FDA as soon as possible but not later than seven (7) calendar days using ADR/AEFI reporting form and submit complete report within eight (8) next calendar days.
6. Progress and final Report of the Clinical Trial shall be submitted to Rwanda FDA at prescribed Timelines

The logo of the Rwanda Food and Drugs Authority (FDA) is centered on the page. It features a stylized face with a yellow and blue vertical bar through the center, set against a background of a laurel wreath. Below the face is a yellow sunburst. The text "RWANDA FDA" is written in large, bold, blue capital letters, and "Rwanda Food and Drugs Authority" is written in smaller, blue, lowercase letters below it.

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