



Kigali on 29/09/2022

Ref. N°: FDISM/PVSM/3772FDA/2022

Ayako KASAI
Chief Executive Officer
Spiker Ltd.
2-5 Inage-ku Chiba-shi, Chiba, Japan
ayako.kasai@spiker.jp

Re: Acceptance letter for insurance waiver

Dear CEO,

Reference is made to your application for letter of August 30th, 2022 requesting for exemption of the submission of an insurance policy cover for trial participants of the trial with Protocol v2.0 entitled “**A Clinical Investigation Evaluating Efficacy of an Intelligent Cardiotocography with Real-Time Alerts for an Improved Labor and Delivery**”;

Reference is also made to the Rwanda FDA regulations No CBD/TRG/015 governing clinical trials in Rwanda, specifically in article 23 paragraph 6 where the Authority may exempt participant insurance after reviewing and analyzing the design and interventions of clinical trials; and the provisions of article 5 of the regulations No CBD/TRG/012Rev_1 governing the registration of medical devices;

Further reference is made to the rule 4 of the guidelines DHT/GDL/024 on submission of Documentation for Registration of Medical Devices;

After analyzing your application and considering the provisions of the above-mentioned regulatory documents, we found that the investigational product is of minimal risk and the Authority hereby guarantees the insurance waiver requested.

Moreover, the Authority reminds you to strictly adhere to GCP-ICH principles and prescribed regulatory requirements regarding the subject's rights, safety, and well-being to ensure the scientific and ethical validity of your study.

Sincerely,

[Handwritten signature]
28/09/2022



Dr. Emile BIENVENU

Director General of RwandaFDA