Enclosed please find a sample letter of authorisation with necessary details:

LETTER OF AUTHORISATION FOR A LEGAL PERSON - SPECIMEN:

Letter of Authorisation

The Sponsor of the clinical trial (hereinafter the "authorising person") <u>give the name of clinical trial</u>, company <u>give the name of the Sponsor</u>, <u>business address and other identification details</u>, <u>e.g. ICO (company identification number)</u>, <u>sponsor's identification number in company register</u>, where available etc.)

hereby authorises

company (hereinafter the "representative") give the name of the authorised company, its business address and other identification details to communicate with the State Institute for Drug Control in the following matter: (e.g. notification, application for authorisation, all operations performed within the above clinical trial etc).

This authorisation is granted for an unspecified/specified period of time. (<u>If the authorisation</u> is granted for a specified period of time the date of expiry of the authorisation period must be <u>stated</u>.).

The representative is authorised to act independently via an authorised person or to grant sub-authorisation to another person or to nominate his employee to act for him on behalf of the authorising person.

Prague, on (date)

Authorising person: legibly indicated name and surname + own signature (No certification of signature is required, however, the Letter of Authorisation must be signed by a person authorised to act on behalf of the authorising person, e.g. company representative, company secretary etc.)

The person receiving authorisation may declare in writing that he/she accepts the authorisation (include date).

Letter of Authorisation

The Sponsor of the clinical trial (hereinafter the "authorising person") give the name of clinical trial, company give the name of the Sponsor, business address and other identification details, e.g. ICO (company identification number), sponsor's identification number in company register, where available etc)

hereby authorises

Mr./Mrs. (hereinafter the "representative") give the full name of the authorised person, his/her place of residence, other identification details where applicable to communicate with the State Institute for Drug Control in the following matter: (e.g. notification, application for authorisation, all operations performed within the above clinical trial etc).

This authorisation is granted for an unspecified/specified period of time. (<u>If the authorisation</u> is granted for a specified period of time the date of expiry of the authorisation period must be <u>stated</u>.)

The representative is authorised to act independently or to grant sub-authorisation to another person to act for him on behalf of the authorising person.

Prague, on (date)

Authorising person: legibly indicated name and surname + own signature (No certification of signature is required, however, the Letter of Authorisation must be signed by a person authorised to act on behalf of the authorising person, e.g. company representative, company secretary etc.)

The person receiving authorisation may declare in writing that he/she accepts the authorisation (include date).