Company headed paper

To the Ministry of Health

General Directorate of Medical Devices and Pharmaceutical Service

Unit 6

Viale G. Ribotta, 5

00144 ROMA[dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it)

SUBJECT: Acquisition of a specific declaration from the manufacturer regarding an authorization request pursuant to Legislative Decree 137/2022, art. 11, paragraph 9, relating to the use of a medical device for which the procedures for the assessment of conformity necessary for the CE marking have not been initiated or completed

The undersigned (first name, surname) ………………………………………………………………….as

legal representative of the manufacturer …………………………………………………………………,

established in………………………………………………………………………………………………,

who intervenes in the procedure as the manufacturer of the following medical device………………………………………………………………………………………………………,

for which prof./dr. …………………………………………………,…,as attending physician, proposed the use, even if in the absence of suitable CE marking, for the patient, of years ........ identified with the acronym (initials of name and surname or other acronym) ....... being treated at the health facility ………………………………………………………………………………………………………....

DECLARES

1. the design and manufacture of the device proposed for use have been carried out under the responsibility of the manufacturer.
2. the use proposed by the attending physician is compatible with the carrying out or completion of conformity assessment procedures.
3. the execution of preclinical tests, at the date of the request, for the intended use proposed by the attending physician,

* *is not planned*
* *is planned but has not been started*
* *is in progress*
* *has been completed*

1. a preclinical evaluation activity, at the date of the request, for the intended use proposed by the attending physician,

* *is not planned*
* *is planned but has not been started*
* *is in progress but the results are not yet available*
* *a preclinical evaluation activity has been carried out and the results are available*

1. a clinical investigation activity, at the date of the request, for the intended use proposed by the attending physician,

* *is not planned*
* *is being prepared*
* *is being approved*
* *has been authorized but has not yet started*
* *has started but is not yet completed*
* *has been completed*

1. the conformity assessment procedures, at the date of the request, for the intended use proposed by the attending physician,

* *have not been started and the proposed intended use and indications are considered not appropriate to the characteristics of the device*
* *have not yet started, even though they are justified by the design and production characteristics of the device*
* *have not yet started, but the manufacturer is preparing the technical documentation for their start*
* *have already started, but have not yet been completed*

1. the information acquired from previous uses, at the date of the request, for the intended use proposed by the attending physician show that,

* *from the use of the device already available on the market of non-EU countries, problems relating to safety have emerged*
* *safety issues have emerged from the use of the medical device available for experimental activities, but corrective actions for their resolution are being applied and defined.*
* *so far no safety aspects for the use proposed by the attending physician have been identified that could compromise the patient’s clinical status or safety*

1. on the market of non-EU countries, the device, for the intended use proposed for the exceptional case in question

* *is not available*
* *is available*

The information that has been provided above regarding the activities planned, started or carried out by the manufacturer for the purposes of conformity assessment, are described and summarized in the following annexes, for each of which the release date and version are specified:

*……………………………………………………………………………………………………………………………..*

In support of the proposed use, clinical data and bibliographic references are also available, for which the following attached documents are provided:

………………………………………………………………………………………………………………..

On the basis of the declarations expressed above and the attached documents, the undersigned therefore declares:

* the proposed use appears compatible with the warnings, precautions, contraindications or other measures to be taken that are provided by the manufacturer
* the potential risks of using the medical device are justifiable considering the expected clinical benefits for the proposed indication of use.

The manufacturer is aware of the fact that the proposed use has been requested with reference to art. 11, paragraph 9, of Legislative Decree 137/2022, which allows in exceptional cases the use, following authorization, of medical devices for which the conformity assessment procedures have not been initiated or completed, for individual patients, in cases of necessity and urgency, in the absence of therapeutic alternatives.

The manufacturer is also aware that the authorization will not be issued with reference to art. 11, paragraph 3, of Legislative Decree 137/2022, relating to the placing on the market or putting into service in derogation and that the authorization does not refer to the supply of the device in the course of a commercial activity.

Date

……………………………………..

|  |  |
| --- | --- |
| Signature of the declarant  ………………………………………. |  |