

**Annex no. 5 of 02/04/2023**

**Study randomized, checked For there assessment from the performance And from the safety Of a device doctor to basic Of acid hyaluronic linear In the treatment from the wounds. WOUND-H study**

**Consent form for the processing of personal data in the context of drug or device trials**

*(to be inserted at the bottom of the sheet containing the information)*

The undersigned....., born in ..... a  
nd  
residing in ....., street/square.....

On their own, i.e.: as the legal representative of

*(Name and surname)*.....,

Born in....., residing in  
.....

(the parent who signs the form in the absence of the other declares, under his/her own responsibility, aware of the provisions of Article 46 of Presidential Decree no. 445/2000, to express the will of both persons exercising parental responsibility)

**STATES**

- that he/she has read the written information above and that he/she has understood both the information contained therein and the supplementary information provided orally by the personnel in charge of the trial;
- that they have received the information in a detailed and comprehensible manner from the doctor requesting the examination and that they have received clear and comprehensive answers to all the questions they have deemed appropriate to ask;
- to be aware that you may change your mind at any time regarding the processing of your personal and sensitive data by communicating your desire to withdraw consent by written notice to.....
- to have been made aware, in writing and orally, of all the rights exercisable pursuant to Article 7, Legislative Decree No. 196 of 30/06/2003 (the so-called Privacy Code), supplemented by Legislative Decree No. 101/2018 adapting to EU Regulation No. 679/2016 (in particular Articles 15 to 22) and the recommendations of the Guarantor for the Protection of Personal Data;

**AND GIVE PERMISSION**

pursuant to Article 23 of the Privacy Code, supplemented by Legislative Decree No. 101/2018 adapting to EU Regulation No. 679/2016 and the recommendations of the Guarantor for the Protection of Personal Data, as well as pursuant to Authorization No. 2/2016 for the processing of data suitable for revealing health and sex life and the "Guidelines for data processing in the context of clinical trials of medicinal products" of 24/07/2008,

*(tick the box of interest with an X and sign in the spaces below)*

- ☐ I hereby consent to my personal data being processed pursuant to Legislative Decree no. 101 of 10 August 2018
- ☐ the processing necessary for the Villa Sofia Rehabilitation Clinic to carry out the experimentation illustrated in detail in points 1 and 2 of the specific "information sheet" describing the experimentation of their personal and health data, which will take place for the purposes, in the forms and in the ways specifically described in points 7 and 8 of the information above;

\_\_\_\_\_, \_\_\_\_\_