**MASKS FOR ASIA**info@masksforasia.com

To:………………………………….(Name of Hospital)

# Declaration of Consent and Application for Compassionate Use of the Easy Covid 19 Mask and Valves (Medical Device) ……………….

**(for more information, visit) https://**[www.isinnova.it/easy-covid19](http://www.isinnova.it/easy-covid19))**[)](http://www.isinnova.it/easy-covid19)) also called the Device**

The undersigned ................................. …........................................born in ………….. on/date ……………………………… , Address & Phone Number………………………………………………………………………

Passport Issued:….. No:………………………..

**Whereas**

* the undersigned is suffering from severe breathing difficulties;
* the undersigned is affected by COVID 19 (or: is awaiting results related to any infection from COVID19);
* according to the so-called Best Practices, in which it is necessary to reduce alveolar compression by using tools or Devices that limit the ease of exhaling during breathing;
* reducing the compression of alveoli slows down the "collapse" of the resulting lung that is derived from the impossibility of the same to expand after the inspiratory phase;
* specific machines are provided for this function,
* however, given the current serious pandemic called COVID19, this hospital does NOT have enough equipment;
* the equipment available to this hospital is already in use by other patients;
* therefore, only the Device referred to in Annexe 1 is available to slow down the execution of exhalation slowing-down manoeuvre

**acknowledges**

* the Device referred to in this request is the result of applying a 3D printed valve to a mask normally used for non-health purposes;
* it is a mask used for "water-level" diving/ snorkelling that is in freely sold in sports shops;
* a 3D printed valve has been applied to the mask respirator which reduces the quantity of air that comes out (reversing the functioning of the valve which is normally applied in ordinary use to prevent water from entering during diving);
* the Device in its original area is suitable for use in water for short durations and not for long periods of time;
* the Device may contain materials that may cause allergies or reactions;
* the Device is not sterilised, but is sanitised;
* the Device has no certification whatsoever for the use that is made following this request (the certifications are issued for the original use as a mask for diving in water and in any case without changing the valve);
* the Device does not guarantee the performance of the equipment normally used in these cases;
* similarly, it also does not meet with certainty the quality, safety and performance requirements of the standard equipment;
* The Device (resulting from the application of the valve to the mask) is very recent, and has not yet received any permissions, regulatory certifications or declarations of compliance of any kind;
* the Device, under the conditions of maximum and unheard of urgency, was subjected to short functional tests;
* therefore, it is not known if and what contraindications or side effects may be
* derived from the use of the Device;
* that other undesirable side effects may occur, which I am committed to report to health professionals in a timely manner;

Given the above, the undersigned acknowledges and declares to have been duly and comprehensively informed about the risks of the Device and to have been informed of the risks of the Device at the same time.

# **requests and authorises the compassionate use of the named Device referred to in Annexe 1**;

# is committed to promptly reporting inconveniences, adverse and undesirable effects to health professionals resulting from the use of the Device itself;

* **indemnifies** the hospital and the subjects who made the changes from any injury or damage that might derive from the use of the Device;
* undertakes to complete any questionnaire related to the Device to assist the tests of the Device and give feedback  
    
    
    
  Date  
    
  Place  
    
    
  Signature