To
ÖTI – Institut für Ökologie, Technik und Innovation GmbH
Notifizierte Stelle NB 0534
Spengergasse 20
A-1050 Wien
AUSTRIA

Application for the implementation of a shortened assessment process for Corona SARS-Cov-2 pandemic respirators (CPA) in accordance with enactment GZ 2020-0.789.415 (= replacement for GZ 2020-0.247.451)

Applicant: .....

(tick the appropriate) ☐ manufacturer / ☐ authorised representative / ☐ importer / ☐ distributor

Authorised signatory: .....

Person in charge: .....

Address (street): .....

Postal code, place, country: .....

Telephone / fax / email: .....

We herewith submit a first application and only to this accredited certifying body for the issue of a letter of assessment in accordance with "Enactment of the Federal Ministry for Digital and Economic Affairs on the Implementation of a shortened assessment process for Corona SARS-Cov-2 pandemic respirators (CPA)" GZ 2020-0.789.415 (= replacement for GZ 2020-0.247.451)
!! After a positive test result without mounted CE marking and only for medical professionals for the duration of the current health threat:
Designation allowing a clear identification of the product within the applicant's company and to be shown both on the product (label, imprint, …) as well as in the technical file (name or item number).

Standards and guidelines applied in the manufacturing of the CPA:

- Enactment GZ 2020-0.789.415 (= replacement for GZ 2020-0.247.451)
- Test principle for Corona SARS-Cov-2 pandemic respirators *(tick the appropriate)*
  ☐ Rev. 0 dated 20.03.2020 ☐ Rev. 1 dated 26.03.2020 ☐ Rev. 2 dated 02.06.2020
- Based on EN 149:2001+A1:2009
- Commission Recommendation (EU) 2020/403 - Conformity assessment and market surveillance procedures within the context of the COVID-19 threat
- Regulation (EU) 2016/425 of the European Parliament and of the Council

Manufacturing company (if other than applicant):	**Manufactured in** (if other than manufacturer's place of business):
.....	.....

The following shall be enclosed with the application:

- At least 5 pieces Corona SARS-Cov-2 pandemic respirators (CPA)
- The technical documentation based on Regulation (EU) 2016/425 Annex III)

Agreement

The following agreement based on to the requirements according EN ISO/IEC 17065:2013

a) The applicant is aware that an application may only be submitted to a body named in the relevant Enactment
b) The applicant is aware that the requirements must always be met, including the implementation of corresponding changes, if these are communicated by the assessment body;
c) The applicant is committed to make all necessary arrangements for
   1. the conduct of the evaluation (see 3.3) and surveillance (if required), including Provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and dient's subcontractors;
   2. investigation of complaints;
   3. the participation of observers, if applicable;
d) The applicant committed that all claims / statements regarding assessment consistent with the scope of the assessment
e) The applicant committed that he does not use its product assessment in such a manner as to bring the assessment body into disrepute and does not make any Statement regarding its product certification that the assessment body may consider misleading or unauthorized;
f) The applicant undertakes in suspension, withdrawal or termination of the assessment to take following required measures:
   1. to stop the use of all advertising materials which contain any reference to the assessment
   2. and shall return all documents requested by the assessment body
   3. and also take care that all other necessary arrangements were realised that no further sales with respect to the assessment takes place
g) The applicant committed that if he provides copies of the assessment documents to others, the documents shall be reproduced in their entirety
h) The applicant committed that in making reference to its product assessment in communication media (eg. documents, brochures or advertising materials) no assessment-certificate or any part thereof will be used in a misleading way
i) The applicant complies to keep a record of all complaints made known to it relating to all compliance with the assessment of requirements and makes these records available to the assessment body when requested, and
   1. takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for assessment;
   2. documents the actions taken;
j) The applicant complies with the commitment to inform the assessment body, without delay, of changes that may affect its ability to conform with the assessment requirements
k) The manufacturer declares that the examination reports submitted refer to the materials used for manufacturing CPA mask.
l) The applicant shall provide the assessment body with the required number of CPA mask in the required sizes.
m) The applicant shall provide sufficient samples of the materials used for necessary laboratory examinations.
n) The applicant agrees that examinations may also be passed on to other recognized or accredited certifying bodies.
o) The applicant declares with his signature that he is not aware of any detrimental health effects of the materials used in the PPE.

Declaration on harmful substances

As a manufacturer and/or person who puts the product on the market I know

- that the a.m. article shall not contain any health impairing concentrations of substances according to annex XIV and XVII of Regulation (EC) No. 1907/2006 (REACH), Regulation (EU) No. 528/2012 (Biocide-Regulation)and Regulation (EC) No. 850/2004 (POP-Regulation).
- that the requirement for PAH (polyaromatic hydrocarbons) in articles to AfPS GS 2019:01 and for PCP according to the German Chemicals Prohibition Ordinance must be fulfilled.
- that materials for PPE should not affect the health or hygiene of the user.
- that materials do not release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful under foreseeable conditions and under normal use.

p) The precise rates for the assessment are known and accepted.
q) Changes affecting the assessment
   1. The applicant is committed to inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the CPA mask with the applicable essential health and safety requirements or the conditions for validity of the letter of assessment.
   2. The applicant commits to inform the assessment body of any changes concerning the client (for example, ownership changes)
r) Confidentiality: The assessment body commits itself that all information which are obtained or created during the assessment activities will be considered as confidential (in accordance with the confidentiality agreement, according to the terms and conditions of our general business terms). Without a prior approval by the customer no content will made publicly available by the assessment body. Excluded are all information that are made available to the public by the customer itself, or when there is an agreement for publication between the client and the assessment body.
s) Information about assessed products: The assessment body is obliged to record information about the assessed products (archiving). On request, the assessment body must inform at least about the validity of a particular assessment. In addition to the purposes of confidentiality [see pt. "Confidentiality"], without previous approval by the customer, no information about the content of the type-examination certificate as well as all documents and samples related will be passed on.

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Place and date Applicant's signature

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