COVID19

suspicious certificates for PPE - updated 05/05/2020

remark: this article is valid for Personal Protective Equipment (PPE), such as protective masks (type FFP2 or FFP3), protective glasses and face shields, protective gloves and garments, etc. The conformity assessment procedures for medical devices (e.g. medical or surgical masks) are different and for those you should seek information from the relevant trade associations or authorities. The manufacturer must also check of other legislation is simultaneously applicable to the product (e.g. REACH is always applicable).

Given the huge amount of requests, we ask you to first read the complete article, before contacting ESF or one of the national trade associations of PPE suppliers. If you have a 'certificate' for PPE that is clearly not from a Notified Body for PPE (this certainly means all institutes from outside EU, Switzerland or Turkey), there is no doubt that the document is not a valid legal base for CE marking.

Everybody is working very hard and with the best intentions to make the necessary PPE available to the healthcare workers and other people involved in the fight against the COVID-19 crisis.

In first instance the Declaration of Conformity (DoC) has to be provided and checked. For products imported from outside the EU (including EFTA and other participants to the single market), the importer has to make sure that the manufacturer has done the conformity assessment as foreseen in the PPE Regulation (EU)2016/425. In case where their is doubt about the DoC or there is no DoC available or there is import from outside the EU, it makes sense or is even necessary to check the certification. See the articles "what to do when importing PPE (e.g. FFP2 masks) to the EU?" and "conformity assessment procedure for PPE"

Unfortunately, we (the European Safety Federation (ESF) = trade association of suppliers of PPE, a not for profit organisation funded by the members) are informed by different sources about 'certificates' or other documents used as basis for CE marking of PPE (including FFP2/FFP3 masks and eye protection), while these 'certificates' have no legal value and can not be used as conclusion of conformity assessment. It is not clear if these documents have actually been issued by the organisations mentioned themselves or if they are fake (we have the impression that **a lot of fake documents** are being presented as proof of compliance). ESF is not accusing them of doing so, we only want to inform and warn about these documents.

Several of the mentioned institutes offer the possibility to check the validity of the 'certificate' on their website. In those cases, a 'valid' response does not make the document a legally valid type examination certificate. It only means that the institute recognises that they have issued the 'certificate' to this producer for the mentioned product.

So far we have seen 'certificates' on letterhead (or using their logo and/or name) of the following institutes based in Europe (examples at the bottom of this page) - the institutes are not a notified body competent for PPE mentioned in the document or the documents are fake :

- ICR Polska see update 31/03/2020, 06/04/2020 and 14/04/2020 below ICR is not a notified body for PPE (they
 are for other products)
- CELAB see statement on their webpage https://celab.com/en/coronavirus/ CELAB is not a notified body for PPE (they are for other products)
- ECM (Ente Certificazione Macchine) also a picture of a mask with identification number of the notified body ECM 1282 next to CE - ECM is not a notified body for PPE (they are for other products), so this marking is certainly not valid) - see update 03/04/2020 below
- ISET (Instituto Servizi Europei Technologici) on their website they have a page with false certificates
 see http://www.iset-italia.eu/index/service/fal.html ISET is Notified Body for some types of PPE, but not for respiratory protection (masks)
- NPS
- · Amtre Veritas
- STS Inspection and Certification
- VIC Testing and Certification
- BSI Test Limited: we have also added an example of a 'certificate of compliance' issued by 'BSI Test Limited,
 London' which is clearly not issued by the Notified Body for PPE BSI and this is confirmed by the Notified Body BSI
 so this one is not a valid EU Type Examination certificate.
- ISP (UK Inspec International): the document as example is titled 'declaration of conformity' but the text refers to 'certificate'
- NTC (Nationaux de Certification Technique CHCS)
- Ecole Supérieure du Bois : This institute provided us the example. The name and address of the Ecole Supérieur du Bois in France is used together with the name Euroscene Business Solutions Limited. The Ecole Supérieure du Bois is active in construction products and confirms that they do not issue certificates for PPE. They have no relationship with Euroscene Business Solutions Limited. This is clearly a **fake** document abusing their name.
- Sapo (Sapo Certification & Testing Laboratory Limited)

We have seen **falsified** (type examination) certificates using the name, logo and/or layout of the following Notified Bodies for PPE (examples at the bottom of this page). These are not issued by themselves, so they are a victim of fraude and can not be blamed for this abuse :

- BSI: we have an example of a BSI EU Type Examination Certificate that has clearly been changed and is thus
 a fake document this is confirmed by the Notified Body for PPE BSI. Certificates of BSI can be verified
 on https://verifeyedirectory.bsigroup.com/
- VUBP (Vyzkumny ustav bezpecnosti prace): we received an example of a 'certificate of conformity' using the name and logo of VUBP. This example has been confirmed by the Notified Body VUBP to be fake
- CSI: CSI sent us an example of a fake certificate for masks using their name and NB number. CSI is a notified body for different types of PPE, but not for respiratory protection. There is no doubt that the example is a fakedocument
- Apave Sudeurope: we received an example of an Apave EU Type Examination certificate this document is not issued by the Notified Body Apave and is confirmed by them to be a **fake** document.

So far we have seen 'certificates' on letterhead (or using their logo and/or name) of the following institutes based in India (examples at the bottom of this page). In any case, a certificate issued by an institute in India is not a legally valid type examination certificate as these can only be issued by a Notified Body with the type of PPE concerned in their scope. So the 'certificates' by such organisations are no legal basis for CE marking nor for placing the PPE on the EU market.

· TQV Certification Services

So far we have seen 'certificates' on letterhead (or using their logo and/or name) of the following institutes based in China (examples at the bottom of this page). Be aware that some of the documents we have seen from Chinese institutes claim FFP2 masks to be PPE category I - this is clearly not correct, protective masks are always PPE category III. Some of the documents are also fake and not issued by the mentioned institute. In any case, a certificate issued by a Chinese institute is not a legally valid type examination certificate as these can only be issued by a Notified Body with the type of PPE concerned in their scope. So the 'certificates' by such organisations are no legal basis for CE marking nor for placing the PPE on the EU market.

- ENC (East Notice Certification Service)
- HTT (Shenzhen HTT Technology)
- · BTK (Guangzhou Bestek Testing Services)
- · Huawin (Shenzhen Huawin Testing Certification)
- LTT (Shengzhen LTT Testing Technology)
- JZ-CERT (Shanghai Jian Zheng Network Technology)
- OCT Technology Testing
- ACT Testing Technology
- XW-CERT (Shenzhen XinWei Certification Service)
- YouBest Testing Technology
- · Shenzhen Tian Hai Test Technology
- BST (BST Testing Service International, Hong Kong)
- CTE (Coffee-T Electronics Technology)
- CTO (Shenzhen CTO Technology Service)
- Huacetong (Shenzhen Huacetong Testing and Certification)
- STA (Shenzhen STA Testing)
- STE (STE Testing Laboratory)
- Bory (Shenzhen Bory Technology Service Co., Ltd.)
- Zuoce (Zuoce Certification and Testing Center)
- HCS (Hwatest Compliance Services Co., Ltd.)
- BEL (Shenzhen BEL Technology Co., Ltd.)
- EUKey (EUKey Testing and Technology Co., Ltd.)

Also 'declaration of conformity' on letterhead of institutes (or using their logo and/or name) that are confirmed by the concerned organisations to be **false** (not issued by themselves, so they are a victim of fraude and can not be blamed for this abuse):

- Nova Certification (based in Greece) the Notified Body Nova (not notified for PPE assessment but for other types of products) confirmed that the example of the 'declaration of conformity' is a **fake** document
- GTS (Global Testing Services, based in China) this organisation confirmed that the example shown is not issued
 by themselves and is thus a **false** document (the reference on the document is an existing reference for a
 document related to a Forehead thermometer and RoHS legislation). On their website http://en.gts-lab.com/ser.htm you can check the reference of the document.

Organisations based in China from which we received information that the example given is not issued by themselves and thus **false**. This means that their name is abused and that they can not be blaimed for this abuse.

- Micez (Shanghai MICEZ Testing & Technical) 14/04/2020 : Micez informed that the example on this page is not issued by Micez and thus **fake**!
- ITC (Shenzhen ITC Product Testing) 18/04/2020: ITC informed that the example on this page is not issued by ITC and thus fake!

- Huaxun (Shenzhen HX Detect Certification) 21/04/2020 : Shenzhen HX Detect Certification informed that the example on this page is not issued by Shenzhen HX Detect Certification and thus **fake**!
- ATL (Shenzhen ATL Testing Technology) 21/04/2020 : ATL informed that the example on this page is not issued by ATL and thus **fake**!
- Beidor (Shenzhen Beidor Testing Technology) 26/04/2020 : Beidor informed that the example on this page is not issued by Beiror and thus **fake**!
- TMC (TMC Testing Services (Shenzhen)) 26/04/2020 : TMC informed that the examples on this page are not issued by Beiror and thus **fake**!
- CCT (Shenzhen CCT Testing Technology) 27/04/2020 : CCT informed that the example on this page is not issued by CCT and thus **fake**!
- CIC (Shenzhen CIC Testing Technology) 27/04/2020 : CIC informed us about a statement on their website clarifying that all certificates issued by CIC for PPE are certainy withdrawn - see http://www.soncap-saso.com/en/article/20200404/503.html
- TXB (TXB Rheinland Testing Services) 28/04/2020 : TXB informed that they never issued CE certificates for PPE and thus that any certificate for PPE with their name on it is **fake**!

We have the impression that manufacturers outside the EU (and probably even 'newcomers' and importers in the EU) are not entirely familiar with the EU Legislation on PPE and thus believe that by paying the 'certificate' from such an organisation, they are fully in compliance with the EU legislation. And most likely, also on the side of the customers (including health authorities), the knowledge about the exact requirements of the EU legislation is lacking and thus they judge those documents as accurate.

It has to be remarked that it is possible that the PPE are safe and offer the claimed protection, even if the documents are not correct and thus offer no solid proof of that. In those cases, testing of the PPE and following the correct procedures can be considered.

At this moment, it is clear that the priority is to get as much as possible masks (and other relevant PPE) into the EU so that the healthcare workers can be protected. On the other hand, it cannot be accepted that sub-standard masks which offer not the claimed protection are made available to healthcare workers that are now at high risk and thus deserve correct protection.

Protective masks (like FFP2/FFP3) are PPE of category III according to the Regulation (EU)2016/425. This means that the conformity assessment includes a type examination by a notified body, resulting in a 'EU type examination certificate' as well as production follow-up by a notified body (random checks or system audit). This results in CE marking with the number of the notified body responsible for the production follow-up next to the CE marking. The manufacturer is obliged to issue the EU Declaration of Conformity, which must accompany (at list via a weblink) the PPE, together with the instructions for use.

Given the current health crisis, the EU Commission published Recommendation (EU) 2020/403 on conformity assessment and market surveillance. This allows for member states to be flexible only for products relevant to the crisis and bought for the duration of the crisis (by authorities) for the healthcare sector. But this does not mean that the products do not have to be in compliance with the applicable essential health and safety requirements defined in the PPE Regulation, and certainly not that they do not need to offer the claimed protection. See for more information on this the article "exceptions to the conformity assessment rules for PPE"

PPE entering the normal distribution chain however, still have to be fully compliant with the Regulation.

For everyone involved: check that 'certificates' you receive for the PPE are correctly titled 'EU type examination certificate' and that they are issued by a competent Notified Body (meaning certainly based in the EU, including EFTA and Turkey). The identification number of the Notified Body has to be included in the EU type examination certificate.

If you have doubts about the Notified Body, you can check the NANDO datebase (https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501) where you will find also the competences of the notified bodies (not all PPE notified bodies are competent for all types of PPE).

If you have doubts about the EU type examination certificate, do not hesitate to contact the notified body concerned with the question if the certificate is genuine and valid to prove compliance to the EU PPE legislation (some of the notified bodies have a tool on their website to check certificates).

In case of doubt or in case of a non legally valid document, you can contact the national market surveillance authorities in the Member State where you are based or where the PPE are destined for.

You can also contact the national organisation of PPE suppliers in your country (see <u>the effective members of ESF for contact information</u>).

For some more information on how to recognise 'misleading' or 'fake' certificates, see also the ESF Q&A 87 and Q&A 88

The China National Accreditation Service (CNAS) has published a list of laboratories accredited for testing of masks (protective and medical) on their website. Remark: Chinese accredited laboratories are certainly not Notified Body for respiratory protection and thus cannot issue EU Type Examination Certificates, they can perform the testing according to the tests for which they are accredited (in the majority of cases this is only to the Chinese standards, not to the EN standards). click here for the list of CNAS

<u>update 31/03/2020 (see also update 06/04/2020 and 14/04/2020)</u>: ICR Polska placed a message on their homepage concerning their voluntary certificates (see https://icrpolska.com/):

Due to the increased interest in obtaining a certificate of compliance with the standards harmonized with the European Commission Regulation on personal protective equipment No. 2016/425, we would like to inform that ICR Polska Co, Ltd. no longer accepts applications for certification on this scope.

At the same time, we explain that, in accordance with the content of issued certificates, the assessments carried out so far are of a voluntary nature and are not equivalent to the mandatory conformity assessment procedures carried out by Notified Bodies authorized to the aforementioned Regulation. These certificates do not confirm conformity with all essential requirements of Regulation No. 2016/425 relating to the product.

<u>update 03/04/2020</u>: ECM sent us the following information concerning the abuse of their notified body number, fake certificates and voluntary certificates:

We would like to state that we are not a Notified Body for PPE and therefore cannot and are not releasing any CE certification for this directive. We are aware of the blatant misuse and forgery of certificates reporting our NB number 1282, like the one you have correctly reported in your article. The use of our name and number on PPE masks is a fraud and an abuse, and we are taking steps to trace and report all fake certificates circulating.

We update our database of fake certificates and the news section of our website almost daily, with any new fakes we discover, but unfortunately it is difficult to trace them all. We also immediately proceed with the required reporting as soon as we get news of a new fake.

To this regard, we would greatly appreciate if you could please let us know the name of the company who is importing PPE masks with our CE number so we can report it immediately. We do not want fake CE certificates with our NB number to circulate, as they risk endangering the users and are a serious issue for our company.

We would also like to underline that any activity performed in regards to the PPE directive has been a voluntary review of technical documentation, and cannot substitute a CE certification in any way. Manufacturers and consultants who have requested this service are aware of the voluntary nature of this type of verification and have agreed on the terms and conditions of the service, conducted according to our voluntary mark regulation, published on our website.

To this regards, we kindly ask you let us know if you encounter any certificates or improper use of our NB number and logo, so that we can proceed reporting it to the authorities.

To this regard, I would like to direct you to our website, where we have addressed (and are continuing to address) the matter in more detail, through the following link: http://entecerma.it/news

update 06/04/2020 : ICR Polska changed the text that was placed on their website on 31/03/2020 - see new update on 14/04/2020.

Dear Sir or Madam,

- you can check the status of the certificate yourself: https://cert.icrpolska.com
- in case of problems with finding the certificate, please attach its scan and send an email to icrpolska@icrqa.com
- at the same time, we would like to inform you, that import of products onto the EU market depends on meeting legal requirements applicable to the product e.g.:
 - Regulation 2016/425
 - Directive 94/42/EEC
- we encourage you to read: https://op.europa.eu/en/publication-detail/-/publication/a247dab0-6794-11ea-b735-01aa75ed71a1/language-en

update 14/04/2020 : ICR Polska changed again the text on their website - see https://cert.icrpolska.com/

annexes to the article (examples of suspicious certificates) can be seen here (click on 'example ...' to open the file) - some of the documents are fake. In any case none of the shown examples are legally valid type examination certificates :

- Celab : example Celab 1 / example Celab 2
- ECM: example ECM / example ECM 2 / picture mask with number of notified body ECM while ECM is not notified for PPE, so invalid marking
- ICR Polska: example ICR Polska 1 / example ICR Polska 2 / example ICR Polska 3 / example ICR Polska 4 / example ICR Polska 5
- ISET: example ISET (this example is one of the many included on the false certificates page of ISET file named
 "Falsa attestazione-certificato kn95.pdf)
- NPS : example NPS

- CIC: example CIC / example CIC 2 see statement about the validity on the website http://www.soncap-saso.com/en/article/20200404/503.html
- Amtre Veritas : <u>example Amtre Veritas</u> (certificate of compliance for safety goggles)
- GTS: example GTS (declaration of conformity) the organisation GTS informed us that this is a fake document that was not issued by themselves ((the reference on the document is an existing reference for a document related to a Forehead thermometer and RoHS legislation)
- Huaxun : <u>example Huaxun</u> (Shenzhen HX Detect Certification informed us that the example not issued by Shenzhen HX Detect Certification and is thus a fake document)
- ENC : example ENC
- STS : example STS
- HTT : example HTT / example HTT 2
- ITC : example ITC (ITC informed us that the example is not issued by ITC and is thus a fake document)
- BTK : example BTK
- Micez: example Micez (Micez informed us that the example is not issued by Micez and is thus a fake document)
- Huawin: example Huawin / example Huawin 2
- LTT : example LTT
- Nova : <u>example Nova</u> (declaration of conformity confirmed by the Notified Body Nova that this is a fake document)
- BSI Test Limited London: <u>example BSI</u> (confirmed by the notified body BSI that this is not a certificate issued by them and thus certainly not a valid EU type examination certificate)
- BSI the Netherlands: <u>example BSI false</u> (confirmed by the notified body BSI that this certificate is altered and thus false)
- VIC : example VIC
- JZ-CERT : example JZ
- OCT : example OCT
- ACT : <u>example ACT</u>
- XW-CERT : <u>example XW</u>
- ATL: example ATL (ATL informed us that the example is not issued by ATL and is thus a fake document)
- TMC: <u>example TMC</u> / <u>example TMC garment</u> (TMC informed us that the examples are not issued by TMC and are thus fake documents)
- YouBest : <u>example YouBest</u>
- Shenzhen Tian Hai Test Technology: example Shenzhen Tian Hai Test Technology
- ISP (UK Inspec International) : <u>example ISP</u> (declaration of conformity)
- VUBP (Vyzkumny ustav bezpecnosti prace): <u>example VUBP</u>(confirmed by the Notified Body that this certificate is not issued by VUBP and thus fake)
- NTC (Nationaux de Certification Technique CHCS) : example NTC
- ESB (Ecole Supérieure du Bois) : <u>example ESB</u> (confirmed by ESB that they do not issue certificates for PPE. This is thus **fake**.
- TQV Certification Services : <u>example TQV</u> (we have hidden the name of the manufacturer and the product reference on request of the manufacturer based in the EU)
- Beidor: example Beidor (Beidor informed us that the example is not issued by Beidor and is thus a fake document)
- BST : example BST
- CCT: example CCT (CCT informed us that the example is not issued by CCT and is thus a fake document)
- CTE : example CTE
- CTO: example CTO
- Huacetong: <u>example Huecetong</u> (declaration of conformity)
- STA: example STA
- STE : example STE
- TXB: example TXB (TXB informed us that the example is not issued by TXB and is thus a fake document)
- CSI: example CSI (confirmed by the notified body CSI that this is a fake certificate)
- Apave : example Apave (confirmed by the notified body Apave that this is a fake certificate)
- Sapo : <u>example Sapo</u>
- Bory : <u>example Bory</u>
- Zuoce : <u>example Zuoce</u>
- HCS : example HCS(goggles)
- BEL : example BEL
- EUKey : example EUKey