

# Assessment report on conformity of personal protective equipment based on Regulation (EU) 2016/425 module C2

<b>Type of personal protective equipment</b>	Protective clothing
<b>Names of the products and EU Type examination certificates and issue dates</b>	Appendix 1
<b>Basis of certification</b>	Regulation (EU) 2016/425 EN ISO 13688:2013 EN 1149-5:2018 EN ISO 11612:2015 IEC 61482-2:2020
<b>Certificate holder</b>	Loxy As
<b>Address</b>	Sørliveien 72 1788 Berg i Østfold Norway
<b>Assessment serial no.</b>	1
<b>Assessor</b>	Seija Ryyänen
<b>Sample collector</b>	Employee of SGS Finland
<b>Sampling date</b>	2023-08-17
<b>Sampling site</b>	Sample was collected from Loxy As, Østfold, Norway
<b>Samples taken</b>	Polo shirt 330393

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## Summary

The module C2 conformity assessment included checking of the design, material, markings, user's instructions, declaration of conformity and testing of the product of EU type-examination certificate. One model was visually inspected and tested.

A total of three non-conformities, which are shown in section 4, were noted at markings, availability and content of user's instructions and declaration of conformity of the inspected product. These findings do not pose a risk to the user. The testing results of the tested item correspond to the performance level of the certificate.

The certificate holder gave a corrective action plan, that is accepted, and implementation will be checked during the next audit. The product is equivalent to the type examined products and fulfills the requirements of module C2 and the essential safety and health requirements of Regulation EU 2016/425

This report has been brought to the attention of the person responsible for the EU-type examination of the products.

Place and date: Helsinki, Finland 2023-09-27



Sanna Karkkula  
Senior Specialist

Next C2 assessment Q3/2024

## 1. Purpose of the assessment

Type assessment certificate holder, who has made a contract with a notified body on product checks in accordance with Regulation (EU) 2016/425 module C2, is responsible for the personal protective equipment conformity to the product described in the certificate and conformity to the essential health and safety requirements of the Regulation. As a part of the conformity assessment procedure, a notified body makes product checks for the personal protective equipment. The checks are made randomly and at least once a year. Valid C2 assessment report may be older than one year because of the variation in time used for testing and checking. Sampling and properties to be tested.

## 2. Sampling and testing plan

Random sampling was carried out at Loxy As, Østfold, Norway. Visual assessment is used to find out if the sampled products are equivalent to the products described in the certificates and fulfill the essential safety and health requirements of Regulation (EU) 2016/425. Item Polo shirt 330393 was selected for testing.

## 3. Checking of the product

Visual inspection of the products was carried out during the audit. The visual checking included: identification, design, color, and materials. Markings and instructions for use were checked from the documentation provided by the manufacturer.

Table 1. Summary of visual inspection, 0598/PPE/22/2437, Issue 1




Property	Finding	Needed correction
Model	Style Polo shirt 330393 is equivalent to the type-examined product.	Nonconforming properties were not found.
Marking	Style Polo shirt 330393 is equivalent to the type-examined product.	Revise and update
User's Instruction	User's Instructions of Polo shirt 330393 needs to be available as a print in the garment bag.	Revise and update
Declaration of Conformity-document	DoC was not received and there wasn't web page information.	Revise and update

Table 2. Summary of test results

Products	Tested property	Evaluation
Style Polo shirt 330393 (48.5% WO, 48.5% VI FR, 3% antistatic, 175 g/m <sup>2</sup> .)	Limited flame spread, seam EN ISO 15025:2016, method A (EN ISO 11612:2015, 6.3 Limited flame spread, code A1).	Limited flame spread of the seam was level A1 as was the level of the type examined model.

The product and test were selected based on the general C2 procedure. Test results applies to all items manufactured with same protective material construction. Testing of the protection against heat and flame was carried out after five domestic washing cycles. Complete testing is presented in test report HELPP2308001670-1, 2023-09-01.

#### 4. Summary of nonconformities

Finding	Corrective action plan from certificate holder 28.8.2023 and 31.8.2023	Assessment 1.9.2023
<b>Markings</b> <ul style="list-style-type: none"> <li>- Product name/number is missing.</li> <li>- CE mark and NB are missing.</li> <li>- Years and classes are missing in pictograms.</li> <li>- Manufacturer with address is missing.</li> <li>- Traceability is missing.</li> </ul>	For the new orders we will use seam label. 	Accepted. Will be reviewed during next audit
<b>User's instruction:</b> <ul style="list-style-type: none"> <li>- Was missing</li> </ul>	We will continue adding user's instruction to every sales package, 	Accepted. Add to the User's instructions where the DoC can be found. Will be reviewed during next audit
<b>Declaration of Conformity (DoC)</b> <ul style="list-style-type: none"> <li>- Was missing</li> </ul>	The DoC will be added on bratens.no website in coming days. 	Accepted. (DoC) document: Supervising C2 NB is not mentioned. Will be reviewed during next audit

End of Assessment report

## Names of the products, EU type examination certificates

Table 1. Products certified according to the Regulation (EU) 2016/425.

EU type examination certificate	Issue date	Expiry date	Notified body	Product name
0598/PPE/22/2437, Issue 1	07.03.2022	06.03.2027	0598 SGS	Polo shirt 330393

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Notified Body 0598

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