

Legal Requirements Assessment Report**1. Orderer**

Name: Dolnośląska Agencja Rozwoju Regionalnego S.A.	Report No.
Address: ul. Szczawieńska 2, 58-310 Szczawno-Zdrój	RWP 26100187.001
Bid number: WA/13557/14	
Application number: 39025695	

2. Manufacturer

Name: HURTOWNIKGROUP Marciniak Sp. J.
Address (fill in if other than in P1) ul. Dekoracyjna 3/B38 65-155 Zielona Góra

3. Product Information

Name	Disposable alcohol content test kit
Product identification, types	„Test & Drive” Alcotest
Product description	Disposable device for controlling alcohol content in exhaled air

4. Assessment of CE marking requirement for “Test & Drive” Alcotest

The operational principles of the system of conformity with general and specific requirements referring to products and the manufacturing processes that can pose risk or are aimed at safety protection or life, health, property or environmental safety are specified in the act of 30 August 2002 on the conformity assessment system.

CE marking indicates the product conformity with EU regulations and therefore facilitates the free flow of products within the European market. By placing the CE mark on a product, manufacturers declare, at their risk, that the products meet all the legal requirements as specified in the CE marking scope.

Not all the products have to be marked with the CE mark. The requirement refers only to product categories under the EU individual directives on CE marking.

CE marking does not indicate that the product is manufactured within the European Economic Area (EEA) but only that it was assessed prior to the market launch and therefore it meets all the valid legal requirements (e.g. concerning the harmonised safety level) to be introduced to the commercial turnover within the EEA. It means that the manufacturer:

- verified the product conformity with all the fundamental requirements (e.g. concerning health, safety and environmental protection) contained in directives concerning the product and
- if assumed in a directive/directives, submitted the product for the assessment by a notified body to verify the conformity.

Considering the declared use of the disposable alcohol test kit and its construction, and after having analysed the legal requirements, we declare that the following product: “Test & Drive” Alcotest” does not meet the criteria of any product group under the New Approach Directive that would require the “CE” marking. Furthermore, there is no standard harmonised with the New Approach Directive that would result in what is called “assumed conformity,” consisting in the assessment that the products that meet the requirements included in national standards implementing the harmonised standards, the numbers of which have been published in the EC Official Journal, are nor compliant with the fundamental requirements.

Accordingly, our opinion is that the disposable “Test & Drive” Alcotest does not require the CE marking.

5. Remarks and comments

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TUV Rheinland Polska Sp. z o.o. Registered Office: u. 17 Stycznia 56, 02-146 Warszawa, phone no.: (22) 846 37 42, e-mail: post@pl.tuv.com		

It is worth noticing that the absence of the CE marking requirement does not exempt the manufacturer from the compliance with safety product requirements.

Directive 2001/95/WE of the European Parliament and Council of 3 December 2001 on general product safety indicates that the product safety should be assessed with due consideration of all the crucial aspects. In the case of absence of particular regulations and in the case of lack of European standards or inability to apply the standards, the product safety should be assessed with special consideration of national standards, being a transposition of other applicable European or international standards, best practices codes and craftsmanship as well as safety levels expected by consumers.

In the case of disposable alcohol tests, the applicable standard can be NF X 20-702:2007 – Determination of alcohol content in exhaled air analysis. It determines technical parameters and test methods being the reference for chemical alcotests to enable the determination of alcohol content in exhaled air and also it provides guidelines for product marking and user manual contents.

6. Report Appendices

n/a

Prepared by

Place/Date 2014.08.26	Signature TUV Rheinland Polska Sp. z o.o. SPECIALIST for Product Certification Krzysztof Świątko [signature illegible]
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Verified by

Place/Date 2014.08.27	Signature TUV Rheinland Polska Sp. z o.o. SPECIALIST for Product Certification Krzysztof Podolec [signature illegible]
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Approved by

Place/Date 2014.08.27	Signature TUV Rheinland Polska Sp. z o.o. SPECIALIST for Product Certification Krzysztof Świątko [signature illegible]
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