



**YOUR BENEFIT - WORLDWIDE**

### BLOOD GLUCOSE MONITORS AND PEN INJECTORS

Millions of people worldwide are affected with diabetes mellitus. Today, these patients can control their disease and effectively prohibit the risk of complications on their health with an accurately functioning Blood Glucose Monitor (BGM) and insulin pen injector.

TÜV Rheinland Nederland B.V. is the leading institute for testing BGM's and pen injector systems. We perform tests for manufacturers in conformity with all relevant and most actual standards, for example in accordance with the TÜV Rheinland Guideline for BGM's and the ISO 11608 series - in compliance with the European medical devices directives.

#### Medical Device Directive

Medical devices such as Blood glucose monitors and pen injectors must be tested on a regular base.

To control the disease and prohibit risks of complications on the health of diabetes patients an accurate functioning Blood Glucose Monitor (BGM) and insulin pen injector are essential.

BGM's and pen injectors are devices that, when used properly by trained individuals, allow the user to monitor and thus to take action to control, their blood glucose (sugar) level. BGM's are used predominantly by individuals effected by diabetes.

Tests of all sorts of pen injectors, (for example: without electronics and replaceable needles, none- replaceable, electronically driven) performed by TÜV Rheinland Nederland B.V. are conform with all relevant and most actual standards and in compliance with the European medical devices directives, offering the flexibility to perform additional tests apart from the standards according to the needs of our clients. TÜV Rheinland Nederland B.V. is constantly following the latest developments in relation to international requirements for pen injector systems and other related devices. We actively take part in the international standardization committees.

#### Why testing and inspection by TÜV Rheinland?

TÜV Rheinland Nederland B.V. is the leading institute for testing BGM and pen injector systems. We know the essence and the backgrounds of the tests that have to be performed in order to show compliance with the standards and directives.

#### Our service to you.

TÜV Rheinland is able to offer the most complete in-house testing package.

TÜV Rheinland Nederland B.V. is operating laboratory facilities to perform tests for BGM's in the field of usability and accuracy of measurement under different circumstances such as climate and influence of environmental radiation. Pen injectors are subject to testing accuracy of measurement. Because almost all tests will be done within the TÜV Rheinland Group, we can easily accommodate our customers' wishes to witness the testing processes for their products. Parts of the BGM tests are performed with Isala Clinics in The Netherlands.

Besides the ability of TÜV Rheinland to perform valid tests in accordance with international standards, we also offer the opportunity to use our testing set-up to perform customer-specific R&D tests under the supervision of one of our experts.

#### Applicable standards for verification

The following standards (voluntary agreements between parties) are used for Blood glucose monitors and pen injector aids and are tested by us on regular basis:

- ISO 15197
- ISO 11608-series
- TÜV Rheinland Guidelines

For a complete overview of our testing portfolio, our capabilities and special test setups please contact us.

#### Unique combination

From our independent position, TÜV Rheinland Nederland B.V. deals with testing and inspection, assessment of dossiers, manuals, user manuals and other texts for BGM's and pen injectors, risk analysis, etc.. We identify all findings in clear and comprehensive reports for you.



#### Please contact us

Are you interested in the complete overview of our products and services in the testing and inspection of blood glucose monitors and pen injectors ?

Then please contact us:

**TÜV Rheinland Nederland B.V.**  
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Phone: +31 88 888 7888  
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## Your Inquiry

e-Mail: [info@nl.tuv.com](mailto:info@nl.tuv.com)

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Yes, I am interested in an offer. Please send me a no-obligation offer!

This concerns the following products \_\_\_\_\_  
\_\_\_\_\_

I send you a photo/image/brochure of/for the product by

fax

e-Mail

regular mail

See for yourself on the Web at: \_\_\_\_\_

Yes, I have a question: \_\_\_\_\_  
\_\_\_\_\_

Yes, I would like to receive further information about similar services by e-Mail.

[info@nl.tuv.com](mailto:info@nl.tuv.com)  
[www.tuv.com/nl](http://www.tuv.com/nl)

## Your contact details

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Company

Importer

Manufacturer

Retailer

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Contact

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Department

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 **TÜVRheinland®**  
Precisely Right.