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# Certificate of Approval

This is to certify that the Management System of:

## ITEST plus, s.r.o.

Kladská 1032/44c, Slezské Předměstí, 500 03 Hradec Králové, Czech Republic

has been approved by LRQA to the following standards:

### ČSN EN ISO 13485:2016

Approval number(s): ISO 13485 – 0058035

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Performing of biological and microbiological testing for clients producing medical devices.  
Sterility test, Determination of bacterial endotoxins, Determination of the population of microorganisms (bioburden), Determination of microbiological contamination of the environment (monitoring), Sampling of air - aeroscope, settle plates, sampling of surfaces - swabs, contact plates.

Production and sale of diagnostic devices in vitro for microbiology.  
Diagnostic discs, Carbohydrates diagnostic tablets, Antimycotic discs, latexagglutination diagnostic sets, other diagnostic discs, diagnostic sera for slide agglutination.



**Paul Graaf**

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Area Operations Manager, Europe

Issued by: LRQA Limited



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# Certificate Schedule

Location	Activities
<p><b>ITEST plus, s.r.o.</b> Kladská 1032/44c, Slezské Předměstí, 500 03 Hradec Králové, Czech Republic</p>	<p><b>ČSN EN ISO 13485:2016</b> Performing of biological and microbiological testing for clients producing medical devices. Sterility test, Determination of bacterial endotoxins, Determination of the population of microorganisms (bioburden), Determination of microbiological contamination of the environment (monitoring), Sampling of air - aeroscope, settle plates, sampling of surfaces - swabs, contact plates.</p> <p>Production and sale of diagnostic devices in vitro for microbiology. Diagnostic discs, Carbohydrates diagnostic tablets, Antimycotic discs, latexagglutination diagnostic sets, other diagnostic discs, diagnostic sera for slide agglutination</p>
<p><b>ITEST plus, s.r.o.</b> Bílá Vchýnice 10 Vápno u Přelouče, Czech Republic</p>	<p><b>ČSN EN ISO 13485:2016</b> Performing of biological and microbiological testing for clients producing medical devices. Sterility test, Determination of bacterial endotoxins, Determination of the population of microorganisms (bioburden), Determination of microbiological contamination of the environment (monitoring), Sampling of air - aeroscope, settle plates, sampling of surfaces - swabs, contact plates.</p>

