



Zertifikat

**CONTOUR® NEXT Messsysteme von Bayer erfüllen
alle Anforderungen der DIN EN ISO Norm 15197:2013.**

- ✓ Systemgenauigkeit durch Fachpersonal
- ✓ Systemgenauigkeit durch Anwender
(ohne vorherige Einweisung)
- ✓ Klinische Systemgenauigkeit
(Error Grid Analyse)
- ✓ Bewertung von Hämatokriteinfluss
- ✓ Bewertung von endogenen und
exogenen Störfaktoren



**Alle CONTOUR® NEXT Messsysteme
verwenden CONTOUR® NEXT Sensoren.**



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Quellen:

- DIN EN ISO Norm 15197:2013 „Testsysteme für die In-vitro-Diagnostik – Anforderungen an Blutzuckermesssysteme zur Eigenanwendung bei Diabetes mellitus“;
Deutsche Fassung; DIN Deutsches Institut für Normung e.V., Beuth Verlag GmbH, 10772 Berlin
- Bernstein R. et al., „A New Test Strip Technology Platform for Self-Monitoring of Blood Glucose“,
J Diabetes Sci Technol, Vol 7: 1386-99 (2013)
- Daniel Brown, Brian Pflug; Accuracy and Precision Evaluation of the Contour® NEXT LINK 2.4 BGMS,
Poster presented at ISPAD, 16.-19.10.13, Gothenburg; Sweden.



**Contour
next**



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Change to Approval Notification - Compliance with ISO 15197:2013

LRQA has reviewed Technical Documentation prepared by Bayer Consumer Care AG and from assessment of the information and results of validation and verification studies submitted, the blood glucose monitoring systems listed below are compliant with the requirements of ISO 15197:2013 and IVD Directive 98/79/EC.

- Contour™ Next
- Contour™ Next USB
- Contour™ Next Link
- Contour™ Next Link 2.4
- Contour™ Plus Link 2.4
- Contour™ XT
- Contour™ Plus
- Contour™ TS, Model 1779A
- Contour™ Model 7220

Yours sincerely,

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