EASD

European Association
for the Study of Diabetes

Medical Devices in Diabetes Care: A statement on behalf of the European Association for the Study of Diabetes

EASD calls for urgent action

It is the position of the EASD that in order to protect people with diabetes, the following actions are essential:

01 Firstly, since the procedure for obtaining a CE Marking and the role of notified bodies have proven to be ineffective, medical devices in diabetes care should be evaluated by independent research institutions. The standard of this evaluation should be the respective ISO-norm.

02 Not only in vitro standards will have to be evaluated but also, and more importantly, real-life settings and situations will need to be evaluated.

03 A continuous post-marketing surveillance of random samples should be a pre-requisite.

1.Saraswati, K., et al (2019, September 1). Quality of medical products for diabetes management: A systematic review. BMJ Global .Health. BMJ Publishing Group.

2.Kingori P, et al. Poor-quality Medical products: social and ethical issues in accessing 'quality' in global health. BMJ Global Health 4;2019:e002151.

3.https://www.easd.org/sites/default/files/Medical_Devices_Statement.pdf

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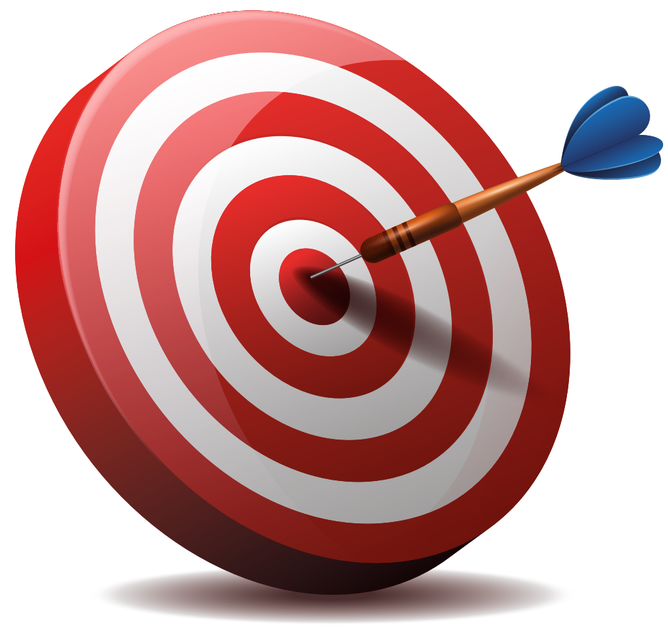
For Better Diabetes Management

Accurate SMBG:

Beyond ISO 15197:2015



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Glucose meter results matter because lives matter

"The availability of inaccurate BGMSs poses a public health problem..."

- Approximately 1/2 of BGMS do not perform up to ISO 15197:2013 standards
- the FDA receives more than 32,000 BGM MDRs per year
- Falsified or degraded/contaminated strips were identified in 29 publication for SMBG supplies quality
- Of the 29 publications on SMBG quality, almost %60 were recalls/alerts

Substandard medical products result from errors, corruption, negligence, or poor practice in manufacturing, procurement, regulation, transportation, or storage.

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Blood Glucose Monitoring Systems Evaluation:

Beyond ISO 15197:2015

Make sure patients are safe and confident

The safety of our patients with diabetes who use devices in their day to day treatment and monitoring is of paramount importance

Steps to BGMS evaluation