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**In vitro diagnostic medical  
devices — Requirements for  
international harmonisation  
protocols establishing metrological  
traceability of values assigned to  
calibrators and human samples**

*Dispositifs médicaux de diagnostic in vitro — Exigences relatives  
aux protocoles d'harmonisation internationaux établissant la  
traçabilité métrologique des valeurs affectées aux étalons et aux  
échantillons humains*

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CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
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