



**CE DECLARATION OF CONFORMITY**

**Manufacturer:**  
Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

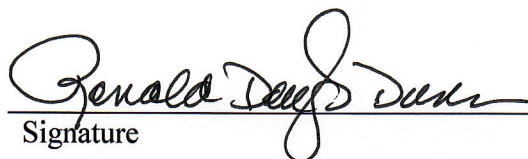
**Authorized Representative:**  
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Vira Solelh  
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France

**Xpert Xpress SARS-CoV-2** (catalogue number XPRSARS-COV2-10) has been tested to the requirements for the following directives and standards. We, the undersigned, hereby declare that the product specified above conforms to the stated directives and standards.

Application of Council Directives, 98/79/EC of the European Parliament and the Council 27 October 1998 on in-vitro medical devices (IVD) in accordance with Annex I and Annex III.

In addition, the above stated product has been manufactured under a certified Quality System compliant with the following standards:

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|--|--|
| EN ISO 13485:2016                      | Medical devices - Quality management systems - Requirements for regulatory purposes.   |
| EN ISO 14971:2012                      | Medical Devices – Application of Risk Management to Medical Devices  |
| EN 13612:2002/AC:2002<br>EN 13641:2002 | Performance evaluation of in vitro diagnostic medical devices<br>Elimination or reduction of risk of infection related to in vitro diagnostic reagents |
| EN ISO 23640:2015                      | In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents   |
| ISO 15223-1:2016                       | Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.   |
| EN ISO 18113:2011                      | In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) Parts 1-3  |

  
Signature

2020 - 05 - 08  
Date

Ronald D. Dunn  
Vice President, Global Regulatory Affairs