Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

EU DECLARATION OF CONFORMITY

We, **Leica Biosystems Nussloch GmbH**, **Heidelberger Str. 17-19**, **69226 Nussloch**, **Germany**

hereby declare under our sole responsibility that the medical products

Product and Trade name	**Leica DB80 HS, Leica DB80 LS, Leica DB80 LX, Leica 818, Leica 819**
Product	Blades without safety systems –single-use
Risk Class	A
Basic UDI-DI	010404918803589W
Single Registration Number	DE-MF-000021943
Product description	A flat, wedge-shaped, sharp blade intended to be mounted into a microtome to cut micro-thin slices of tissue that has been fixed, and usually impregnated, with paraffin wax. The resulting sections are mounted onto slides for staining and then viewing with a microscope. This is a single-use device.

meet the provision European legislation:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (OJ L 117, 5.5.2017, p. 176–332). The procedure according to Annex II and Annex III of the above-mentioned regulation has been followed.

  EN ISO 14971:2019

Quality Management System: Certified according to EN ISO 13485:2016 and ISO 9001:2015

Manufacturing site: Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany

This declaration is effective for products placed on the market as of the date of issue. Any modification of the device not authorized by Leica Biosystems will invalidate this declaration.

Nussloch, 28.04.2022

Andreas Eich
Senior Director CH Nussloch

Robert Gropp
RA/QA Director

Rev. E