EU Technical Documentation Assessment Certificate

This is to certify that the company

WILDmedical GmbH

Ehrenbergstraße 18
78532 Tuttlingen
Germany

SRN: DE-MF-000017096

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIb and III as listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	31621214 MDR2017P
Certificate ID	1000153473
Effective date	2023-12-14
Expiry date	2028-12-13
Frankfurt am Main,	2023-12-14

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.92 Version 5.0

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000017096
Certificate ID: 1000153473

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Disposable Bioptome
Models:	n/a
Risk classification:	III
Basic-UDI-DI:	426235778MW011008S
Intended purpose:	Disposable bioptomes are used exclusively for the removal of tissue samples from the heart (endoscopic myocardial biopsy) so that complications, such as rejection reactions after transplant, can be identified at an early stage.

Examinations and tests performed:
549162_A212657MED dated 2023-12-06

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	n/a	n/a	n/a