



EU Quality Management Certificate



This is to certify that the company

Clouz GmbH

Schinkestr. 9
12047 Berlin
Germany

SRN: DE-MF-000007330

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III 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 Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	548826 MDR2017Q
Certificate ID	170780845
Effective date	2025-06-12
Expiry date	2030-06-11
Frankfurt am Main,	2025-06-12



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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 the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007330
Certificate ID: 170780845

Device categories and variants covered by this certificate:

Produktkategorie: **MDN 1104 – Non-active soft tissue and other implants**
Produktbezeichnung: Clouz OneKnot Polyester
Risikoklasse: IIb
Basis-UDI-DI: 426074624clz1kUB
Zweckbestimmung: Clouz OneKnot Polyester is intended for use in general soft tissue approximation and/or ligation, excluding any use in cardiovascular, ophthalmic and neurological procedures. Clouz OneKnot Polyester delivers a single knot and is intended for single use only.

Examinations and tests performed:

548826_A210950MED_01 dated 2023-05-16

548826_A210950MED_02 Clouz OneKnot Polyester dated 2025-05-27

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
n/a	n/a	n/a	n/a