



EU Quality Management Certificate



This is to certify that the company

PICTERUS AS

Kjøpmannsgata 61
7011 Trondheim
Norway

SRN: NO-MF-000002136

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.	549089 MDR2017Q
Certificate ID	1000189527
Effective date	2024-07-24
Expiry date	2026-10-27
Frankfurt am Main,	2024-07-24



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



Annex to EU Quality Management Certificate
SRN of Manufacturer: NO-MF-00002136
Certificate ID: 1000189527

Device categories and variants covered by this certificate:

Device category: **MDA 0315 - Software**
Product name: Picterus Jaundice Pro
Risk classification: IIa
Basic-UDI-DI: 707308701PicterusL6
Intended purpose: The Picterus® Jaundice Pro is intended to assist in screening and follow up for neonatal jaundice by optical measurement of bilirubin levels from pictures of the newborn's chest, where the Picterus Calibration Card is placed.

Examinations and tests performed:

549089_A208431MED_420_11e_Report_MED_2021-10-18 dated 2021-10-22
549089_A209952MED_01 dated 2022-03-05
549089_Report-Technical-File-Review_Picterus-Jaundice-Pro_2 dated 2021-07-16
549089_A210785MED_01 dated 2022-10-23

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	2022-03-17	170779050	Extension of the indication of the app (user group)
02	2022-12-02	170781888	New certificate template and change of address