EU Quality Management Certificate

This is to certify that the company

PICTERUS AS

Havnegata 7
7010 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. Limitations to this certificate are listed in the Annex.

Certificate registration no.	549089 MDR2017Q
Certificate ID	170781888
Effective date	2022-12-02
Expiry date	2026-10-27
Frankfurt am Main,	2022-12-02

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body
(active medical devices)

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

Annex to EU Quality Management Certificate
SRN of Manufacturer: NO-MF-000002136
Certificate ID: 170781888

Device categories covered by this certificate:

Device category:	**NON-INVASIVE BILIRUBIN SCREENING DEVICE**
Risk classification:	Class lla
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

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

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)