



# 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



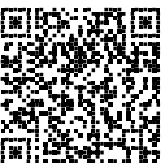
Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-094

## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
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.



**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 IIa  
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:**

<b>Revision</b>	<b>Date of Issue</b>	<b>Certificate-ID</b>	<b>Description of change</b>
01	2022-03-17	170779050	Extension of the indication of the app (user group)