



# EU Technical Documentation Assessment Certificate



This is to certify that the company

## PICTERUS AS

Havnegata 7  
7010 Trondheim  
Norway

SRN: NO-MF-000002136

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.

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

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

Certificate registration no.	549089 MDR2017B
Certificate ID	170781887
Effective date	2022-12-02
Expiry date	2026-10-25
Frankfurt am Main,	2022-12-02



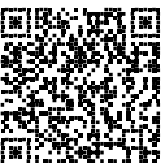
Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-094

## 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 Technical Documentation Assessment Certificate**  
**SRN of Manufacturer: NO-MF-000002136**  
**Certificate ID: 170781887**

**Device categories and variants covered by this certificate:**

Device category: **NON-INVASIVE BILIRUBIN SCREENING DEVICE**  
Product name: Picterus Jaundice Pro  
Models: n/a  
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\_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:**

Products listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

**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	170779051	Extension of the indication of the app (user group)