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
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Head of Certification Body
(non-active medical devices)

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:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-17	170779051	Extension of the indication of the app (user group)