EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000007042)

NEXUS / ASTRAIA GmbH

Adalperostraße 80
85737 Ismaning
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-10-31	Registration No.	D1165200022
Valid until:	2027-10-13	Evaluation Report No.	P23-00461-282400

Stuttgart, 2023-10-31

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: NEXUS / GEBURTSHILFE CTG-Überwachung (ARGUS)

Intended purpose: NEXUS / GEBURTSHILFE CTG-Überwachung (ARGUS) is a patient monitoring software for gynaecological clinics. It is used to collect vital parameters of mother and child during labour and display them online on standard PCs. The data collection itself is done with CTG devices (cardiotocographs), which digitize the raw data and transmit them to NEXUS / GEBURTSHILFE CTG-Überwachung.

With the help of additional options, NEXUS / GEBURTSHILFE CTG-Überwachung can store the digitized data together with patient information, exchange data with other software products in the NEXUS product family or with hospital information systems.

Optionally, the recorded data can be analyzed. The following options are available for this purpose:

- Alerting on the basis of fetal or maternal threshold values
- Calculation of a score based on the FIGO guidelines
- Calculation of short term variations (STV)

NEXUS / GEBURTSHILFE CTG-Überwachung can be installed as a stand-alone or network system. This allows the user to monitor the CTG curves of several pregnant women simultaneously from one location. This makes it possible to assess the condition of the unborn child and the mother.

Risk class: IIb

Product: astraia - software for women's health

Risk class: IIa

Product: NEXUS / GEBURTSHILFE CTG-Übersicht-App

Risk class: IIa

Product: NEXUS / GEBURTSHILFE Pränatal Ultraschall (SonoGeb)

Risk class: IIa

Notes:

The certificate is based on the previous certificate D1165200021 dated 19.09.2023 with the following changes:
Supplemented by the products:
NEXUS / GEBURTSHILFE CTG-Überwachung (ARGUS), NEXUS / GEBURTSHILFE CTG-Übersicht-App and
NEXUS / GEBURTSHILFE Pränatal Ultraschall (SonoGeb)