EG-Konformitätserklärung für Medizinprodukte

entsprechend der Verordnung (EU) 2017/745 (MDR)

Declaration of conformity for medical devices

according to Annex I of Regulation (EU) 2017/745 (MDR)

CE 0483

NEXUS / ASTRAIA GmbH

Adalperostraße 80, D-85737 Ismaning, Germany

SRN: DE-MF-000007042

Wir erklären hiermit in alleiniger Verantwortung, dass das Produkt
We hereby declare under our sole responsibility, that product

Produkt & Handelsname / *Product & tradename*

astraia - software for women's health - obstetric and gynaecological database application Version 29.0.0 Device Identifier: 2110 - 6161	Basis UDI-DI / *Basic UDI-DI*: 426074885ASTRAIASC

auf das sich diese Erklärung bezieht, die Forderungen der Verordnung (EU) 2017/745 (MDR) über Medizinprodukte erfüllen. Das Produkt gehört zur Risikoklasse IIa nach Anhang VIII.
to which this declaration relates is in conformity with the requirements of the Regulation (EU) 2017/745 (MDR). The product belongs to risk class IIa according to Annex VIII.

Konformitätsbewertungsverfahren gemäß der Verordnung (EU) 2017/745 (MDR) Anhang IX
Conformity Asessment Route according to the Regulation (EU) 2017/745 (MDR) Annex IX.

Das Unternehmen unterhält ein QM-System gemäß den Anforderungen der DIN EN ISO 13485.
The organisation supports a QM-system according to the requirements of DIN EN ISO 13485.

Ferner wurde das Risikomanagement nach DIN EN ISO 14971:2020 durchgeführt.
Furthermore risk management has been carried out according to DIN EN ISO 14971:2020.

Benannte Stelle / *Notified Body 0483*
mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, Germany

Ismaning / *Ismaning*, 2022-11-24

Dr. Uwe Hannemann – General Manager NEXUS / ASTRAIA GmbH

Zweckbestimmung / Intended use

Intended use / medical indication

- Structured documentation of patient data and history, examination details, findings, diagnoses, management and therapy information
- Creating and sharing structured examination reports / printouts
- Monitoring fetal and maternal health
- Detection of abnormal fetal growth
- Prediction of fetal trisomy 18 and 13
- Prediction of preeclampsia
- Prediction of fetal growth restriction
- Prediction of preterm delivery
- Prediction of malignancy of ovarian masses
- Exchanging data with ultrasound devices (i.e. transfer of measurement data and images to the astraia software)
- Exchanging data with laboratory devices (i.e. transfer of analyte concentrations to the astraia software)
- Exchanging data with hospital information systems (HIS), picture archiving and communication systems (PACS), Laboratory information system (LIS) and other IT systems in a medical facility
- View, adjust, measure and categorise DICOM media directly in the examination record
- Collecting and extracting data for (clinical) studies, quality control and performance statistics

Contraindications

The astraia software offers clinical decision support but does not provide automatic diagnosis, decisions or management and treatment information.

Intended patient group

Sex: Women

Conditions: Pregnant and non-pregnant

Age: From early adulthood on

Ethnic origin: No restrictions

Health: Healthy and unhealthy subjects

Weight: No restrictions

Probable body part

The product is a pure software and is therefore not applied in or on the human body.

However, within its intended use / medical indication (see above), the astraia software takes into account the following parts and properties of the human body:

- Female (reproductive) organs and fetal anatomy
- Blood
- Maternal and fetal physiology
- Genetic information about the mother and fetus

Probable user profile

Doctors (e.g. Gynaecologists, Obstetricians) Radiologists, Sonographers, Midwifes, Secretaries, Medical assistants, Laboratory staff, IT-personal

User Qualification

Secondary school education (ISCED 2), basic software skills, basic astraia software application training

The use of the FMF risk algorithm to predict trisomy 18, 13 preeclampsia, fetal growth restriction and preterm delivery requires a valid FMF license that is provided by the Fetal Medicine Foundation directly!

Intended environment of use

Type of environment

Medical examination room, doctor's office, nurse desk, administrative office, delivery room

Technical environment

Computer hardware, IT- systems and softwares, ultrasound machines, laboratory devices

Physical environment

Not applicable as the product is a pure software.

Clinical environment

Not applicable as the product is a pure software.