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to whom it may concern

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30.04.2021

Astraia software and the included available FMF algorithm 2018

Herewith we confirm that

- astraia - software for women's health database application (version 1.27.0 or higher)
- astraia FMF- First Trimester Screening for Trisomy 21 (Version 4.0 or higher)

are not comparable with the application 'The First Trimester Screening Program 2012' what is available on the hompage of the FMF UK (www.fetalmedicine.org) which is free of charge.

The 'astraia FMF- First Trimester Screening for Trisomy 21' is, together with the risk-calculation for:

- trisomy 13 and 18
- preeclampsia
- IUFT
- fetal growth restrictions

part of the software application astraia - software for women's health database application.

The software, available on the FMF UK homepage is outdated. All documents available in connection with this application are not longer valid as they has to be renewed in defined time intervals.

The current versions of that documents are sent together with this declaration.

Comparison of Features

	Astraia Obstetrics	FMF FTS
Complete demographic patient data documentation	***	***
Documentation of antenatal history and diagnostic findings	***	*
Indication	***	*
Ultrasound examination of the fetus (early pregnancy, 1st, 2nd and 3rd Trimester, biometry, anatomy, Doppler, detailed anatomy)	***	* (only 1st trimester)
1st Trimester Risk calculation for chromosomal anomalies (FMF UK registered users)	*** FMF 2018 algorithm	*** FMF 2012 algorithm
PE Screening	PE Screening in 1st, 2nd and 3rd trimester	PE Screening in 1st trimester only
2nd Trimester risk of trisomy 21	***	-
Reference selection for charts	***	-
Fetal and maternal assessment	***	-
Maternal ultrasound examination	***	-
Complete documentation of all (non) invasive diagnostic procedures	***	-
Examination of placenta	***	-
Detailed documentation of laboratory results	***	* (only 3 parameters)
Diagnosis, Conclusion, Outcome	***	*
Creation of Reports	***	***
Clinical Diary	***	-
Statistic Module: interactive query module	***	*
Audit trail Module: quality management review	***	-

Screen Configuration	***	-
Network option	***	-
other modules:	gynaecology, colposcopy, breast, delivery, fetal echocardiography, fetal neurosonography, MRI	-
Other functionalities:	Interfaces to Hospital or clinical information systems, laboratory systems, image and measurement data transfer from ultrasound machines	-

*** Fully integrated

* Basic information only

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Business Manager

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Software Astraia a zahrnutý dostupný algoritmus FMF 2018

Tímto to potvrzujeme, že

- astraia - software women´s health database application (verze 1.27.0 nebo vyšší)
- astraia FMF-First Trimester Screening for Trisomy 21 (verze 4.0 nebo vyšší)

nejsou srovnatelné s aplikací „The First Trimester Screening Program 2012", která je k dispozici na domovské stránce FMF UK (www.fetalmedicine.org) zdarma.

The „astraia FMF – First Trimester Screening for Trisomy 21" je, společně s kalkulátorem rizika pro:

- trisomii 13 a 18
- preeklampsii
- IUFT
- omezení růstu plodu

součástí softwaru „astraia – software for women´s health database application".

Software dostupný na domovské stránce FMF UK je zastaralý. Všechny dokumenty dostupné v souvislosti s touto aplikací již nejsou platné, protože musí být obnovovány v definovaných časových intervalech.

Současné verze těchto dokumentů jsou odesílány společně s tímto prohlášením.

Porovnání funkcí

	Astraia porodnický modul	FMF FTS
Kompletní dokumentace demografických údajů o pacientech	***	***
Dokumentace prenatální historie a diagnostických nálezů	***	*
Indikace	***	*
Ultrazvukové vyšetření plodu (rané těhotenství, 1., 2. a 3. trimestr, biometrie, anatomie, Doppler, detailní anatomie)	***	* (pouze 1. trimestr)
Výpočet rizika chromozomálních anomálií v 1. trimestru (registrovaní uživatelé FMF UK)	*** FMF 2018 algoritmus	*** FMF 2012 algoritmus
PE Screening	PE Screening v 1., 2. a 3. trimestru	PE Screening pouze v 1. trimestru
Riziko trizomie 21 v 2. trimestru	***	-
Možnost výběru a nastavení grafů (studií)	***	-
Hodnocení plodu a matky	***	-
Těhotenské ultrazvukové vyšetření	***	-
Kompletní dokumentace všech ne-invazivních diagnostických výkonů	***	-
Vyšetření placenty	***	-
Podrobná dokumentace laboratorních výsledků	***	* (pouze 3 parametry)
Diagnóza, závěr, výsledek	***	*
Vytváření zpráv	***	***
Klinický deník	***	-
Statistický modul: interaktivní dotazovací modul	***	*
Modul Audit Trail: přehled řízení kvality – auditní záznam	***	-
Konfigurace obrazovky	***	-
Provoz v počítačových sítích	***	-

Další moduly:	gynekologický, kolposkopie, vyšetření prsu, porodnický, fetální echokardiografie, fetální neurosonografie, MRI	-
Další funkcionality:	Rozhraní k nemocničním nebo klinickým informačním systémům, laboratorním systémům, přenos obrazových a měřicích dat z ultrazvukových strojů	-

*** Plně integrováno
* Pouze základní informace

EG-Konformitätserklärung für Medizinprodukte

entsprechend der Richtlinie 93/42/EWG Anhang II

Declaration of conformity for medical devices

according to guideline 93/42/EEC appendix II

CE 0483

astraia software gmbh

Occamstraße 20, D-80802 Munich, Germany

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

Produkte, Bezeichnung / *Products, name*

astraia - software for women's health
- obstetric and gynaecological database application
Version 1.27.0
Device Identifier: 2110 - 6161

auf das sich diese Erklärung bezieht, die Forderungen der Richtlinie 93/42/EWG über Medizinprodukte erfüllen. Das Produkt gehört zur Risikoklasse IIa nach Anhang IX.
to which this declaration relates is in conformity with the requirements of the directive 93/42/EEC. The product belongs to risk class IIa according to appendix IX.

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

Ferner wurde das Risikomanagement nach EN ISO 14971:2013 durchgeführt.
Furthermore risk management has been carried out according to EN ISO 14971:2013.

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

München / *Munich*, 13.12.2019

Roland Denk – General Manager

EG-Konformitätserklärung für In-vitro-Diagnostika

entsprechend der Richtlinie 98/79/EG Anhang IV

EC Declaration of conformity for in vitro diagnostic devices

according to guideline 98/79/EC appendix IV

CE 0483

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

Produkte, Bezeichnung / *Products, name*

astraia FMF – First Trimester Screening for Trisomy 21
Version 4.0
Device Identifier: 2110 – 2161

auf das sich diese Erklärung bezieht, die Forderungen der IVD Richtlinie 98/79/EG erfüllt.
to which this declaration relates is in conformity with the requirements of the directive 98/79/EC.

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

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

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

München / *Munich*, 15.02.2019

Roland Denk – General Manager

Certificate

mdc medical device certification GmbH
certifies that

astraia software gmbh
Adalperostraße 80
85737 Ismaning
Germany

for the scope

Clinical Database Application
- Development, Consulting, Realisation -

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-04-20
Valid until	2022-03-31
Registration no.	D1165200016
Report no.	P21-00262-198258
Stuttgart	2021-04-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

astraia software gmbh
Adalperostraße 80
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Germany

for the scope

astraia - software for
women's health, obstetric and gynaecological database application

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-04-20
Valid until	2024-01-23
Registration no.	D1165200018
Report no.	P21-00262-198265
Stuttgart	2021-04-20

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

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EC Certificate

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Notified Body 0483
herewith certifies that

astraia software gmbh
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Germany

for the scope

astraia FMF – First Trimester Screening for Trisomy 21

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2021-04-20
Valid until	2024-01-23
Registration no.	D1165200017
Report no.	P21-00262-198263
Stuttgart	2021-04-20

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-247.10.05

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