

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**NEXUS / ASTRAIA GmbH**  
**Adalperostraße 80**  
**85737 Ismaning**  
**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	2022-05-23
Valid until	2025-05-26
Registration no.	D1165200019
Report no.	P22-00372-230276
Stuttgart	2022-05-23

  
Head of Certification Body

