DIRECTA

EU Declaration of Conformity

Manufacturer	**DIRECTA AB** Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999501AL
Product and trade name	**CoForm™**
Product code/REF	604036, 604037, 604038, 604039, 604040, 604041, 604042, 604043, 604044, 604045, 604046, 604047, 604048, 604049, 604050, 604051, 604035, 604034
Intended purpose	Pre-shaped matrix to form acrylic or composite fillings. Intended user is professional licensed dentist.
Risk Class	Class I, rule 5
Common specification (CS)	N/A
Notified body	N/A
Conformity Assessment Procedure	Article 52, paragraph 7
Statement	This EU declaration of conformity is issued by under the sole responsibility of Directa AB. The device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices.

Upplands Väsby, 2021-05-18

Henric Karsk
CEO

First version of EU Declaration of Conformity (MDR) issued year 2021.
TF13.1_DoC_EN_2021-05-18

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