DENTSPLY

Dyract XP

Declaration of Conformity

We

DENTSPLY DeTrey GmbH
De-Trey-Strasse 1
78467 Konstanz
Germany

declare under our sole responsibility that the products listed below to which this declaration relates were developed, produced and controlled in application to Council Directive 93/42/EEC of 14 June 1993 concerning medical device / Annex I and II.3 as amended by Council Directive 2007/47/EC – including its transposition in national laws. The products fulfil the essential requirements according to Directive 93/42/EEC Appendix I. The assessment of Conformity was accomplished with regard to all applicable harmonized standards. This declaration of conformity is valid for all batches manufactured after the date of issue.

List of products:

606.04.210	Dyract XP – Starter Kit
606.04.275	Dyract XP – Refill A2
606.04.276	Dyract XP – Refill A3
606.04.277	Dyract XP – Refill A3.5
606.04.278	Dyract XP – Refill B1

This product is classified as a Class IIa Medical Device under Annex IX Section III, rule 8, implantable device, long-term use.

Notified Body:	TÜV SÜD PRODUCT SERVICE GMBH, Ridlerstraße 65, 80339 München,Germany CE 0123
EC Certificate:	G1 09 10 21108 018
Valid until:	2014-11-30

Konstanz, 12.07.2013
(Place and date of issue)
DENTSPLY DeTrey GmbH

Dr. Elke Barsties
Manager Regulatory Affairs