

DICHIARAZIONE DI CONFORMITA' CE
EC DECLARATION OF CONFORMITY
N° CEI - A003 - 09

Noi / We :

Società / Company :

ADLER ORTHO S.P.A.

Via dell'Innovazione 9

20032 Cormano (MI)

ITALY

Tel. + 39 02 61 54 37 1

Fax + 39 02 61 54 37 222

Dichiariamo ed assicuriamo sotto la nostra responsabilità che i dispositivi medici denominati stelo HYDRA e HYDRA-FIX, la cui lista è qui allegata, appartengono alla Classe III e soddisfano le disposizioni ad essi applicabili del Decreto Legislativo 46/97, che traspone nella legislazione italiana la Direttiva 93/42/CEE del 14 giugno 1993 e successive modifiche inclusa la Direttiva 2007/47/CE del 5 settembre 2007.

Dichiariamo ed assicuriamo inoltre che :

- La marcatura CE dei dispositivi di Classe III, la cui lista è qui allegata, è stata apposta in conformità con la procedura prevista nell'Allegato II (incluso il punto 4) del Decreto Legislativo 46/97.
- La nostra Società ha messo in atto un sistema qualità conforme all'Allegato II del Decreto Legislativo 46/97 (Sistema Completo di garanzia di qualità).
- In accordo con le disposizioni del Decreto Legislativo 46/97, il nostro sistema qualità è sottoposto ad approvazione e sorveglianza di un organismo notificato.

Declare and assure under our own responsibility, that all medical devices named HYDRA and HYDRA-FIX stem, listed in the product list here enclosed, belong to Class III and meet the applicable provisions of the Italian Decree 46/97 transposing into the Italian legislation Directive 93/42/EEC of 14 June 1993 and its further amendments including Directive 2007/47/EC of 5 September 2007.

Moreover we declare and assure that:

- *The CE marking of the Class III medical devices listed in the product list here enclosed, has been affixed following the procedure referred to in Annex II (including point 4) of the Italian Decree 46/97.*
- *Our Company has put in place a quality system that complies with the Annex II of the Italian Decree 46/97 (Full quality assurance System).*
- *According to the dispositions of the Italian Decree 46/97, our quality system is approved and supervised by a notified body.*

Lista dei dispositivi medici soggetti all'apposizione della marcatura CE

List of medical devices subject to the affixing of CE marking

Reference	Description
0107100	HYDRA CEMENTLESS STEM SIZE 8
0107101	HYDRA CEMENTLESS STEM SIZE 9
0107102	HYDRA CEMENTLESS STEM SIZE 10
0107103	HYDRA CEMENTLESS STEM SIZE 11
0107104	HYDRA CEMENTLESS STEM SIZE 12
0107105	HYDRA CEMENTLESS STEM SIZE 13
0107106	HYDRA CEMENTLESS STEM SIZE 14
0107107	HYDRA CEMENTLESS STEM SIZE 15
0107108	HYDRA CEMENTLESS STEM SIZE 16
0107109	HYDRA CEMENTLESS STEM SIZE 17
0107110	HYDRA CEMENTLESS STEM SIZE 18

Reference	Description
0187300	HYDRA CEMENTED STEM SIZE 8
0187301	HYDRA CEMENTED STEM SIZE 9
0187302	HYDRA CEMENTED STEM SIZE 10
0187303	HYDRA CEMENTED STEM SIZE 11
0187304	HYDRA CEMENTED STEM SIZE 12
0187305	HYDRA CEMENTED STEM SIZE 13
0187306	HYDRA CEMENTED STEM SIZE 14
0187307	HYDRA CEMENTED STEM SIZE 15
0187308	HYDRA CEMENTED STEM SIZE 16
0187309	HYDRA CEMENTED STEM SIZE 17
0187310	HYDRA CEMENTED STEM SIZE 18

Reference	Description
0107700	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 8
0107701	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 9
0107702	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 10
0107703	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 11
0107704	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 12
0107705	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 13
0107706	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 14
0107707	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 15
0107708	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 16
0107709	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 17
0107710	HYDRA-FIX CEMENTLESS STEM NECK 12/14 STANDARD SIZE 18

Reference	Description
0107800	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 8
0107801	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 9
0107802	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 10
0107803	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 11
0107804	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 12
0107805	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 13
0107806	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 14
0107807	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 15
0107808	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 16
0107809	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 17
0107810	HYDRA-FIX CEMENTLESS STEM NECK 12/14 WITH OFFSET SIZE 18

Reference	Description
0187700	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 8
0187701	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 9
0187702	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 10
0187703	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 11
0187704	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 12
0187705	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 13
0187706	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 14
0187707	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 15
0187708	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 16
0187709	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 17
0187710	HYDRA-FIX CEMENTED STEM NECK 12/14 STANDARD SIZE 18

Reference	Description
0187800	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 8
0187801	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 9
0187802	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 10
0187803	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 11
0187804	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 12
0187805	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 13
0187806	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 14
0187807	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 15
0187808	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 16
0187809	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 17
0187810	HYDRA-FIX CEMENTED STEM NECK 12/14 WITH OFFSET SIZE 18

Date : 04/09/2017

Il Direttore Operativo
Operations Manager
Patrizio Cremascoli

