

**DICHIARAZIONE DI CONFORMITA' CE**  
*EC DECLARATION OF CONFORMITY*  
**N° CEI - A007 - 06**

Noi / We :

Società / Company :

**ADLER ORTHO S.P.A.**

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**ITALY**

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Dichiaro ed assicuro sotto la nostra responsabilità che i dispositivi medici denominati **TESTE CERAMICHE**, la cui lista è qui allegata, appartengono alla Classe III e soddisfano le disposizioni ad essi applicabili del Decreto Legislativo 46/97, che trasporta 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.

Dichiaro ed assicuro 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 CERAMIC HEADS, 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*

<b>Reference</b>	<b>Description</b>
0510281	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 28 SHORT
0510282	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 28 MEDIUM
0510283	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 28 LONG
0510321	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 32 SHORT
0510322	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 32 MEDIUM
0510323	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 32 LONG
0510361	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 36 SHORT
0510362	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 36 MEDIUM
0510363	FORTE ALUMINA CERAMIC HEAD 12/14 DIAM 36 LONG
0514281	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 28 SHORT
0514282	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 28 MEDIUM
0514283	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 28 LONG
0514321	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 32 SHORT
0514322	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 32 MEDIUM
0514323	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 32 LONG
0514361	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 36 SHORT
0514362	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 36 MEDIUM
0514363	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 36 LONG
0514401	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 40 SHORT
0514402	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 40 MEDIUM
0514403	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 40 LONG
0514441	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 44 SHORT
0514442	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 44 MEDIUM
0514443	DELTA ALUMINA CERAMIC HEAD 12/14 DIAM 44 LONG

Reference	Description
0511321	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 32 SHORT
0511322	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 32 MEDIUM
0511323	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 32 LONG
0511361	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 36 SHORT
0511362	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 36 MEDIUM
0511363	FORTE ALUMINA CERAMIC HEAD 10/12 DIAM 36 LONG
0512221	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 22 SHORT
0512222	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 22 MEDIUM
0512223	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 22 LONG
0512281	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 28 SHORT
0512282	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 28 MEDIUM
0512283	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 28 LONG
0512321	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 32 SHORT
0512322	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 32 MEDIUM
0512323	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 32 LONG
0512361	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 36 SHORT
0512362	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 36 MEDIUM
0512363	DELTA ALUMINA CERAMIC HEAD 10/12 DIAM 36 LONG

Reference	Description
0513281	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 28 SHORT
0513282	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 28 MEDIUM
0513283	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 28 LONG
0513284	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 28 EXTRA LONG
0513321	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 32 SHORT
0513322	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 32 MEDIUM
0513323	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 32 LONG
0513324	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 32 EXTRA LONG
0513361	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 36 SHORT
0513362	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 36 MEDIUM
0513363	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 36 LONG
0513364	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 36 EXTRA LONG
0513401	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 40 SHORT
0513402	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 40 MEDIUM
0513403	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 40 LONG
0513404	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 40 EXTRA LONG
0513441	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 44 SHORT
0513442	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 44 MEDIUM
0513443	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 44 LONG
0513444	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 44 EXTRA LONG
0513481	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 48 SHORT
0513482	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 48 MEDIUM
0513483	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 48 LONG
0513484	DELTA ALUMINA CERAMIC REVISION HEAD 12/14 DIAM 48 EXTRA LONG
0513280	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 28
0513320	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 32
0513360	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 36
0513400	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 40
0513440	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 44
0513480	MODULAR DELTA ALUMINA CERAMIC REVISION HEAD DIAM 48
0513001	MODULAR SLEEVE 12/14 FOR REVISION HEAD SHORT
0513002	MODULAR SLEEVE 12/14 FOR REVISION HEAD MEDIUM
0513003	MODULAR SLEEVE 12/14 FOR REVISION HEAD LONG
0513004	MODULAR SLEEVE 12/14 FOR REVISION HEAD EXTRA LONG

Date : 04/09/2017

**Il Direttore Operativo**  
Operations Manager

Patrizio Cremascoli

