

# Herstellerbescheinigung

Manufacturer Certification



Hersteller: Manufacturer:	SIRONA Dental Systems GmbH
Adresse: Address:	Fabrikstraße 31 64625 Bensheim
Medizinprodukt: Medical device:	Autoklav  DAC Universal, D 3472

We declare the conformity of the DAC Universal to  
**EN 13060 type S**

for steam sterilisation of

- T1 Classic S40L and T2 Racer from SIRONA,
- Intramatic Lux 3 und Gentleforce 7000B from KaVo,
- Synea WA 56 LT, Prophy Axis and Synea TA 98 from W&H and
- dental instruments, which are comparable concerning weight, materials and geometry.

Furthermore, the full program cycle includes a cleaning function which has been verified according to


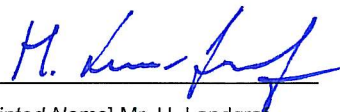
**ISO/TS 15883-5:2005 Annex J**

regarding the internal and external cleaning of the tested straight, contra-angle and high-speed handpieces as well as of solid instruments placed in a basket.

According to the German RKI-Guideline ( Richtlinie des Robert-Koch-Instituts) „Infektionssprävention in der Zahnheilkunde – Anforderungen an die Hygiene“ from 2006

it is possible to treat dental instruments with the DAC Universal in the risk evaluations

**semi critical A and B as well as  
critical A und B if used immediately.**

Bensheim, den: <u>11.6.2012</u>	
Ort und Datum/Place and date	
 [Unterschrift/Signature]	 [Unterschrift/Signature]
[Name in Druckschrift/Printed Name] Mr. J. Siefert Geschäftsbereichsleiter Instrumente/ Vice President Instruments Division	[Name in Druckschrift/Printed Name] Mr. H. Landgraf Approbations-Ingenieur/Approval-Engineer