



Extra note for GP-04-drill bath PLUS IM 400-03-08-01-ZA01_Master label drill bath PLUS DB 400)

Example label with mandatory details, area of validity: European Union


Classified as a class IIb medical product

Laws/Directives/Standards:

	Description	Text	Legal basis	Evidence for the statement
1	Product name	Drill bath PLUS DB 400	1272/2008/EC	
2	Product description and intended purpose ¹	<p>Type of application: For the cleaning and prophylactic disinfection of dental drills and rotating instruments. Notes on application: Always use the PLUS drill bath undiluted! After use, put the instruments straight into the ready-for-use solution, all the parts to be disinfected have to be fully covered. At the earliest after the application time, remove all the parts from the bath, rinse with water and dry. Do not mix with other disinfectants or cleaning agents. Cannot be used for aluminium. It is recommended to wear protective gloves and eye protection. Application times: Bacteria (EN 13727, EN 14561 and VAH, high contamination): Conc.: 5 min. Candida albicans (EN 13624, EN 14562, VAH, high contamination): Conc.: 5 min. TbB (M. terrae) as per EN 14348 and EN 14563, low contamination: Conc.: 5 min. Enveloped viruses (e.g. HBV, HCV and HIV) as per RKI/DVV (high contamination): Conc.: 5 min. (high contamination)</p>	EEC 93/42 (G: Medical Device Law [EN: Medical Product Law])	See assessments and test reports under 12.1 of the product documentation
3	Safety guidelines	<p>Safety guidelines: H412 Harmful to aquatic organisms, with long-term effect. Avoid release to the environment. Dispose of the contents/container in accordance with local/regional/national/international regulations.</p>	1272/2008/EC	
4	Ingredients as per 648/2004/EC	<p>Directive 648/2004/EC: Contains < 5% non-ionic surfactants, <5% cationic surfactants surfactants, <5% EDTA salts, fragrance.</p>	648/2004/EC	
5	CE marking with the number of the nominated office	CE0124	EEC 93/42	
6	Contents (volume)	XXXXml / XXltr. e	1272/2008/EC; 67/211/EEC	
7	Batch number and best before date	 See imprint	EEC 93/42; EN 15223-1, EN 980	
8	Date of editing (in format CCYY-MM)	2017-06	EEC 93/42 (2007/47/EC)	
9	Storage conditions	 40°C 0°C	EN 15223-1, EN 980	

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¹ Text can vary

10	Name and address of the distributor, incl. tel. no. & symbol		1272/2008/EC, EEC 93/42; EN 15223-1, EN 980
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* X = Filler text

Extra voluntary details:

- 11:** Notice: Additional information for "product usage" can be copied from point 71. from technical documentation.
- 12:** range of activity:
bactericidal (incl. MRSA) acc. EN 13724, EN 14561, VAH; yeasticidal (*Candida albicans*) acc. EN 13624, EN 14562, VAH; tuberculocidal (*M.terrae*) acc. EN 14348, EN 14563, partially virucidal (membrane covered viruses e.g. HBV, HIV, HCV) acc. DVV/RKI
- 13:** "100g contain:": 0,396g Didecyldimethylammoniumchlorid 0,2475g N-(3-Aminopropyl)-N-dodecyl-propan-1,3-diamin.
- 14:** **time of activity:**
Bacterias acc. EN 13727 (high bio load):
100% 1min.
Candida albicans acc. EN 13624 (high bio load):
100% 1min.
Bakterien acc. EN 14561 (high bio load):
100% 5min.
Candida albicans acc. EN 14562 (high bio load):
100% 1min.
Bacterias and Candida albicans acc. VAH (high bio load):
100% 5min.
TbB (*M. terrae*) acc. EN 14348, EN 14563 (low bio load):
100% 5min
„partially virucidal“ (membrane covered viruses acc. RKI/DVV e.g. HBV, HCV, HIV), high bio load:
12% 5min.
- 15:** If an article number is to be applied, this must have "REF" next to it (EN 15223-1, EN 980)
- 16:** Barcode

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