



## Media Release

Zurich – 25 June 2007

### **Swedish Medical Product Agency reconfirms safety and efficacy of NobelDirect and NobelPerfect one-piece implants**

**As announced today the Swedish Medical Product Agency (MPA) has accepted Nobel Biocare's action plan with some additional clarifications. Nobel Biocare welcomes the renewed confirmation of market clearance without constraints by the MPA for NobelDirect™ and NobelPerfect™ one-piece implants.**

The comprehensive scientific evidence that Nobel Biocare provided to the MPA proved the product safety and effectiveness of NobelDirect™ and NobelPerfect™ one-piece implants. The prospective multi-center study and additional extensive scientific documentation representing 1973 implants followed up to 6 years have led the MPA to reconfirm their decisions of February 2006 and December 2006 and to reiterate the market clearance for both products. The Company is pleased that a conclusion was found after a 19-month process.

The MPA had requested specifying references to the products' procedures manuals, for which Nobel Biocare has outlined an action plan to respond to the open questions. The MPA has accepted Nobel Biocare's action plan with some additional clarifications, which will be implemented immediately. Nobel Biocare has continuously worked with the MPA in a joint effort to ensure and further enhance the safety and effectiveness of NobelDirect™ and NobelPerfect™ one-piece implants. The Company has voluntarily put the promotional material of the said products on hold in August 2006 and will continue to do so until further notice.

During the entire process, Nobel Biocare received broad support by dental professionals, academic experts, and universities from all over the world to underline the success and effectiveness of the aforementioned products. To date, more than 100,000 NobelDirect™ implants have been successfully placed. Furthermore, NobelDirect™ implants display very good success rates compared to any other implant on the market and its product quality was never questioned. The allegations against the products have been fully refuted.

Nobel Biocare is confident that its leading role in mentoring, training and education and scientific evidence will help to further raise the industry standard of product introduction monitoring and documentation.

**NOBEL BIOCARE HOLDING AG**



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**Nobel Biocare** is a medical devices group and the world leader in innovative esthetic dental solutions with its brands Brånemark System<sup>®</sup>, NobelReplace<sup>™</sup>, NobelSpeedy<sup>™</sup>, NobelPerfect<sup>®</sup>, NobelDirect<sup>®</sup>, Replace Select, (dental implants), Procera<sup>®</sup> (individualized dental prosthetics), NobelGuide<sup>™</sup> (complete patient rehabilitation program) and NobelSmile<sup>™</sup> (patient education website). Nobel Biocare is a one-stop shop for restorative esthetic dentistry, offering a wide range of innovative Crown & Bridge & Implant products, as well as training and education, patient information and clinically documented treatment concepts. Nobel Biocare has over 2,100 employees and recorded revenue of EUR 601 million in 2006. The Company is domiciled in Zurich, Switzerland with headquarters in Zurich and in Gothenburg, Sweden. Production takes place at four production sites located in Sweden and the USA. Nobel Biocare has direct sales organizations in 34 countries. The shares of the parent company Nobel Biocare Holding AG are listed on the SWX Swiss Exchange and on the Stockholm Stock Exchange, Sweden.

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