**FINANCIAL DISCLOSURES**

***【配合Financial Certification一起使用】***

(*参考示例：{公司名称} is submitting clinical data to support this 510(k) notice, and is providing its disclosure of financial interest as required by 21 C.F.R. § 54.4 below.*

*The two studies evaluating the {器械名称} for fat and circumference reduction were conducted in house at one site in Israel (Syneron’s in house clinic) by employees of {公司名称}. Per FDA’s guidance, “Financial Disclosure by Clinical Investigators,” no financial disclosure certification is needed for clinical investigators who are employees of the sponsor. Nonetheless, it should also be noted that there are no concerns regarding potential bias in the studies, as demonstrated by the consistent trends in the data showing circumference and fat reduction across multiple different assessments. Further, results were similar between the two {器械名称} studies as well as when compared to the results of the predicate (e.g., abdominal circumference reduction at last follow up of -2.15 cm ({器械名称}, 3 bi-weekly treatments), -1.84 cm ({器械名称}, 2 monthly treatments), and - 1.47 cm (Transcend predicate)).*

*In addition, the investigator who performed the treatments was different from the person who performed the measurements in the study. In addition, the device was evaluated for the histological effects on skin and subcutaneous fat. The study was conducted at the Rabin Medical Center in Israel under the supervision of Dr. Dean Ad-El. The signed certification below certifies that no disclosable financial arrangements were entered into with the clinical investigator of this study.*)

***【资料中含有临床试验数据，需要提供Financial Certification 和/或 Financial Disclosures。可以参考14-2-1\_Financial Certification和14-2-2 Financial Disclosures提供的模板提供，也可以结合实际情况，参考FDA最新的 FDA\_3454 Financial Certification和FDA\_3455 Financial Disclosures表，填写相应的信息，并提供对应的资料。***

***其中FDA\_3454 Financial Certification和FDA\_3455 Financial Disclosures表，需要在最新的Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s指南中下载，FDA表格会不定期更新】***